North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 2, 2015

La Bommie Saunders, Office Manager
Planned Parenthood Of Wilmington
1925 Tradd Court
Wilmington, NC 28401

Re: State Licensure Survey

Dear Ms. Saunders,
Thank you and your staff for the assistance and cooperation extended during the state licensure survey at Planned Parenthood Of Wilmington in Wilmington, NC on June 17, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Licensing . As discussed at the exit conference, state licensure deficiencies were identified with respect to 10A NCAC 14E .0305 Medical Record and 10A NCAC 14E .0314(b) Cleaning of Materials and Equipment.

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form CMS 2567, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,
Joyce Spinicchia
Joyce Spinicchia, RN, BSN
NurseConsultant
Acute and Home Care Licensure and Certification Section

Enclosures: State Form - Statement of Deficiencies

RECEIVED AUG 17 2015

8/17/15

PRINTED: 07/20/2015
FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered. This Rule is not met as evidenced by: Based on closed medical record review and staff interview, the facility failed to maintain a complete medical record that includes a physician signature on the voluntarily-signed surgery consent form in the patient's permanent medical record for 4 of 10 records reviewed (Patients #6, 7, 8, & 10). 1. Closed medical record review of Patient #6 revealed a 31 year-old who had a surgical abortion or '15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature	E 137	10A-14E .0305(A) At Planned Parenthood South Atlantic (PPSAT), patient signatures on consents for surgical and medication abortions require a witness by trained staff members. Prior to and after each procedure, physicians review and sign off on the patient's medical record to ensure histories are reviewed, required examinations are performed, voluntary consents are obtained, and patient consent process is witnessed as per NCDHHS regulations. As of 5/11/15, PPSAT revised abortion consent procedures to include physician signature on abortion consent forms (see attached CIIC-022 and CIIC-027). PPSAT provided a thorough training for all staff, including physicians providing abortions, 6/18/2015. The health center manager will review all charts at the end of each clinic day to ensure compliance with physician signatures on CIIC-022 and CIIC-027 forms. Daily monitoring will continue until consistent compliance is demonstrated. Regional Lead Clinician will conduct an audit of 10 charts at the end of three months to ensure compliance. Quarterly monitoring will continue until consistent compliance is demonstrated.	6.18.2015

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Vice President of Patient Services 8/3/15

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 1 was obtained. 2. Closed medical record review of Patient #7 revealed a 24 year-old who had a surgical abortion on /15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature was obtained. 3. Closed medical record review of Patient #8 revealed a 22 year-old who had a surgical abortion on /15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature was obtained. 4. Closed medical record review of Patient #10 revealed a 24 year-old who had a surgical abortion or /15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature was obtained.	E 137		
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and	E 165	10A-14E .0314 On June 18, 2015 a new refrigerator was purchased for Wilmington, NC health center.	6.18.15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 2 equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on observation during tour, the facility failed to properly store medications in a manner to prevent possible cross contamination with biohazardous material. The findings include: Tour of the facility on June 17, 2015 at 1000 revealed the medication refrigerator also housed a cardboard box in the door which stored patient blood samples waiting to be sent out for laboratory results. The tour also revealed there is a biohazard refrigerator where products of conception (POC) are kept post procedure waiting for disposal. Interview with the Regional Director on June 17, 2015 at 1430 revealed she was aware of how the medication refrigerator was being used and understands the contamination issue. Interview confirmed the medication refrigerator was also being used to store patient blood samples waiting to be sent out for laboratory testing.	E 165	Health center staff has reviewed PPSAT Infection Prevention Policy and Procedures mandating medications and blood products, including blood samples, must be stored in separate refrigerators. The health center now has 2 separate refrigerators: one for the storage of medications and one for the storage of blood products including blood samples. In addition, appropriate storage of POC was reviewed with health center staff. As per PPSAT Infection Prevention Policies and Procedures, staff will continue storing POC in a separate freezer that is used solely for this purpose. Health Center Manager will monitor the correct, separate storage of medications and blood products, including POC, during monthly health center Infection Prevention checks. Regional Lead Clinician will monitor when performing quarterly site visits. The following statement, as found in E 165 is a statement of fact that on site reviewers observed: "the tour also revealed there is a biohazard refrigerator where products of conception (POC) are stored post procedure waiting for disposal." Reviewers did not find inappropriate storage of POC during their site visit.	Reviewed June 4, 2015 during staff meeting.

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 10, 2015

Rachel Hales, Associate Administrator
A Preferred Womens' Health Center
3320 Latrobe Drive
Charlotte, NC 28211

RE: Complaint investigation NC00107392

Dear Ms. Hales:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the survey conducted June 16, 2015 through June 17, 2015. The purpose of conducting the complaint survey was to evaluate the compliance of the clinic with North Carolina Rules Governing the Certification of Clinics for Abortions. As discussed in the exit conference, there were 1 complaint with 1 allegation which was unsubstantiated. There were no deficiencies cited as a result of the investigation.

Should you have questions concerning the investigation, please do not hesitate to call me at (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN,
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

Enclosed: State Form

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0055	A. BUILDING: _____ B. WING _____	C 06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS An unannounced complaint investigation was conducted on 06/16/2015. No deficiencies identified. The allegation was unsubstantiated. NC00107392	E 000		

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

April 27, 2015

Rachel Hales, Administrator
A Preferred Women's Health Center
2460 Curtis Ellis Drive
Charlotte, NC 28211

RE: Recertification and Complaint survey Survey NC00093728, NC00090314, NC00095741, NC00091024

Dear Ms. Hales:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the Survey conducted February 10, 2015 through February 11, 2015. The purpose of conducting the survey was to evaluate the Clinic's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortion. Based on survey findings and further in office review no deficiencies will be cited.

Should you have questions concerning the investigation, please do not hesitate to call me at (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

Enclosed: State Form

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	55 AB0032	A. BUILDING: _____ B. WING _____	C 02/11/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS An unannounced complaint investigation and recertification survey was conducted 02/10/2015 through 02/11/2015. No deficiencies cited. NC00091024 NC00093728 NC00090314 NC00095741	E 000		

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

State Form: Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
ab0015	A. Building B. Wing	9/10/2014

Name of Facility	Street Address, City, State, Zip Code
A WOMAN'S CHOICE OF GREENSBORO	2425 RANDLEMAN RD GREENSBORO, NC 27406

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix E0131 Reg. # .0302 LSC	Correction Completed 09/10/2014	ID Prefix E0147 Reg. # .0306(B) LSC	Correction Completed 09/10/2014	ID Prefix E0150 Reg. # .0306(E) LSC	Correction Completed 09/10/2014
ID Prefix E0151 Reg. # .0307 LSC	Correction Completed 09/10/2014	ID Prefix E0159 Reg. # .0312(A) LSC	Correction Completed 09/10/2014	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By State Agency	Reviewed By	Date:	Signature of Surveyor:	Date:
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:	Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO
5/9/2014	

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 27, 2015

Shannon Morgan, Administrator
A Preferred Women's Health Center
1604 Jones Franklin Road
Raleigh, NC 27606

RE: State Licensure Survey

Dear Ms. Morgan:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the State Licensure Survey conducted July 16, 2015. The purpose of conducting the survey was to evaluate the facility's compliance with the North Carolina Rules for Licensing Abortion Clinic.

As discussed in the exit conference, there were no deficiencies cited as a result of the survey.

Should you have questions concerning the investigation, please do not hesitate to call me at (919) 218-9458.

Sincerely,

Lynn Ethridge, RN, BSN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 9, 2015

Gloria Davila, Clinic Manager
A Woman's Choice Of Raleigh, Inc
3305 Drake Circle
Raleigh, NC 27607

Re: Recertification Survey

Dear Ms. Davila,

Thank you and your staff for the assistance and cooperation extended during the Recertification survey at A Woman's Choice Of Raleigh, Inc in Raleigh, NC from May 13, 2015 through May 14, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Certification of Abortion Clinics. As a result of the survey, deficiencies were identified with respect to .0304 Grievance Process, .0303 Policy/Procedures, .0305 Consent/Physicial Examination and .0311 Examination of the POC.

Enclosed please find STATE Form , "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies should be submitted and include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.

(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and

(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form State Form, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

Enclosures: State Form Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

√CBB 08/10/2015

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 132	.0303 POLICIES AND PROCEDURES 10A-14E .0303 The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include: (1) Patient selection and exclusion criteria, and clinical discharge criteria. (2) Policy and procedure for each type of abortion procedure performed at the clinic. (3) Protocol for determining fetal age. (4) Protocol for referral of patients for whom services have been declined. (5) Protocol for discharge instructions that informs patients who to contact for post-procedural emergencies. This Rule is not met as evidenced by: Based on policy and procedure reviews and staff interviews the Governing Authority failed to prepare a policy for patient selection and exclusion criteria. The Findings include: Review of the Clinic Policy and procedure manual did not reveal any documentation of a policy addressing the patient selection and exclusion criteria. Interview with the Office Manager on 05/14/2015 at approximately 1145 revealed there was no documentation available of a clinic policy addressing patient selection and exclusion	E 132	See Attachment Tag E132	6/15/15

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Office Manager 8/5/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 132	Continued From page 1 criteria.	E 132		
E 136	.0304(D) ADMISSIONS AND DISCHARGE 10A-14E .0304 (d) Following admission and prior to obtaining the consent for surgery required by Rule .0305(a) of this Section, representatives of the clinic's management shall provide to each patient the following information: (1) A fee schedule and any extra charges routinely applied, (2) The name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included; (3) Instructions for post-procedure emergencies as outlined in Rule .0313(d) of this Section; (4) Grievance procedures a patient may follow if dissatisfied with the care and services rendered; and (5) The telephone number of the Complaints Investigation Branch of the Division. This Rule is not met as evidenced by: Based on Clinic Patient's Rights Documentation review and staff interview the clinic failed to have a system/process in place providing patients the Grievance procedures a patient may follow if dissatisfied with the care and services rendered; and The telephone number of the Complaints Investigation Branch of the Division. The Findings include:	E 136	See Attachment Tag E136	7/13/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 2 Review of the Clinic's "PATIENT RIGHTS DOCUMENT" revealed "To file a complaint call: (919) 733-8499, North Carolina Health & Human Services. Complaint Instigation". Interview with the Office Manager on 05/13/2015 at 1500 revealed the clinic staff does not give the patients information on how to file a complaint with the clinic or the telephone number of the Complaints Investigation Branch of the Division. The interview revealed the clinic has Patient Rights documentation but the information is not given to the patient. The interview revealed the staff do not verbally inform the patient of the information contained on the Clinic's Patient's Rights	E 136		
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered.	E 137	See Attachment Jas E 137	7/13/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 3 This Rule is not met as evidenced by: Based on closed medical record reviews, staff interviews and physician interviews, the clinic staff failed to maintain a completed permanent record including a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination in 6 of 6 Surgical Abortions procedures (SAB) completed. (#'s 1, 4, 6, 5, 3 and 2). The findings included: 1. Review of medical record #1 revealed the patient had a SAB completed on 05/13/2015. Record review did not reveal documentation of a witnessed, voluntarily-signed consent for the surgical procedure and signature of the physician performing the procedure. Record review did not reveal documentation of the physician's authenticated history and physical examination. Interview with the Clinic Manager on /2015 at 1605 revealed there was no documentation available of a witnessed, voluntarily-signed consent for the surgical procedure with signature of the physician performing the procedure. The interview revealed there was no documentation of the physician's authenticated history and physical examination. The interview revealed the history is performed by the technician. 2. Review of medical record #4 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation of a witnessed, voluntarily-signed consent for the surgical procedure and signature of the physician	E 137		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 4 performing the procedure. Record review did not reveal documentation of the physician's authenticated history and physical examination. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available of a witnessed, voluntarily-signed consent for the surgical procedure with signature of the physician performing the procedure. The interview revealed there was no documentation of the physician's authenticated history and physical examination. The interview revealed the history is performed by the technician. 3. Review of medical record #6 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation of a witnessed, voluntarily-signed consent for the surgical procedure and signature of the physician performing the procedure. Record review did not reveal documentation of the physician's authenticated history and physical examination. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available of a witnessed, voluntarily-signed consent for the surgical procedure with signature of the physician performing the procedure. The interview revealed there was no documentation of the physician's authenticated history and physical examination. The interview revealed the history is performed by the technician. 4. Review of medical record #5 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation of a witnessed, voluntarily-signed consent for the surgical procedure and signature of the physician performing the procedure. Record review did not reveal documentation of the physician's	E 137		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 5 authenticated history and physical examination. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available of a witnessed, voluntarily-signed consent for the surgical procedure with signature of the physician performing the procedure. The interview revealed there was no documentation of the physician's authenticated history and physical examination. The interview revealed the history is performed by the technician. 5. Review of medical record #3 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation of a witnessed, voluntarily-signed consent for the surgical procedure and signature of the physician performing the procedure. Record review did not reveal documentation of the physician's authenticated history and physical examination. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available of a witnessed, voluntarily-signed consent for the surgical procedure with signature of the physician performing the procedure. The interview revealed there was no documentation of the physician's authenticated history and physical examination. The interview revealed the history is performed by the technician. 6. Review of medical record #2 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation of a witnessed, voluntarily-signed consent for the surgical procedure and signature of the physician performing the procedure. Record review did not reveal documentation of the physician's authenticated history and physical examination.	E 137		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 6 Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available of a witnessed, voluntarily-signed consent for the surgical procedure with signature of the physician performing the procedure. The interview revealed there was no documentation of the physician's authenticated history and physical examination. The interview revealed the history is performed by the technician. Interview with Physician #1 on 05/14/2015 at 1040 revealed he performs abortion procedures at the clinic. The interview revealed he was the physician performing SABs today in the clinic. The interview revealed he does not complete a physical examination on the patient. The interview revealed if the patient had a any significant history he would not do the SAB at the clinic. The interview revealed since the SAB is an elective procedure he does not examine the patient prior to the SAB.	E 137		
E 158	.0311(B) SURGICAL SERVICES 10A-14E .0311 (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) The facility shall have written procedures, supplies and equipment available for gross and microscopic	E 158	See Attachment Tag E158 5/17/15	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 7 evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C. (3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record. (4) The facility shall establish procedures for obtaining, identifying, storing and transporting specimens. (5) The facility shall establish a method for follow-up of patients on whom no villi are seen. This Rule is not met as evidenced by: Based on policy and procedure review, closed medical record reviews, staff interviews and physician interview, the physician performing the surgical abortion procedure (SAB) failed to examine the products of conception (POC) prior to the patient discharge in 6 of 6 patients having a SAB (#'s 1, 4, 6 , 5, 3 and 2). The findings include: Review of the clinic's current policy titled "Products of Conception Examination Procedure September 22, 2002" revealed no documentation	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 8 addressing the requirement for the physician to examine the POC prior to the patients' discharge. 1. Review of medical record #1 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation the physician performing the surgical abortion procedure (SAB) examined the products of conception prior to the patient discharge. Review of the medical record revealed documentation of examination of the POC completed by the technician. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available the physician performed an examination of the POC. The interview revealed the technician performs the examination of the POC. The interview revealed the physician only examines the POC if asked by the technician. The interview revealed the technician performing the examination of the POC was the standard of practice for the clinic. 2. Review of medical record #4 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation the physician performing the surgical abortion procedure (SAB) examined the products of conception prior to the patient discharge. Review of the medical record revealed documentation of examination of the POC completed by the technician. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available the physician performed an examination of the POC. The interview revealed the technician performs the examination of the POC. The interview revealed the physician only	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 9 examines the POC if asked by the technician. The interview revealed the technician performing the examination of the POC was the standard of practice for the clinic. 3. Review of medical record #6 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation the physician performing the surgical abortion procedure (SAB) examined the products of conception prior to the patient discharge. Review of the medical record revealed documentation of examination of the POC completed by the technician. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available the physician performed an examination of the POC. The interview revealed the technician performs the examination of the POC. The interview revealed the physician only examines the POC if asked by the technician. The interview revealed the technician performing the examination of the POC was the standard of practice for the clinic. 4. Review of medical record #5 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation the physician performing the surgical abortion procedure (SAB) examined the products of conception prior to the patient discharge. Review of the medical record revealed documentation of examination of the POC completed by the technician. Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available the physician performed an examination of the POC. The interview revealed the	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 10	E 158		

technician performs the examination of the POC. The interview revealed the physician only examines the POC if asked by the technician. The interview revealed the technician performing the examination of the POC was the standard of practice for the clinic.

5. Review of medical record #3 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation the physician performing the surgical abortion procedure (SAB) examined the products of conception prior to the patient discharge. Review of the medical record revealed documentation of examination of the POC completed by the technician.

Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available the physician performed an examination of the POC. The interview revealed the technician performs the examination of the POC. The interview revealed the physician only examines the POC if asked by the technician. The interview revealed the technician performing the examination of the POC was the standard of practice for the clinic.

Review of medical record #2 revealed the patient had a SAB completed on /2015. Record review did not reveal documentation the physician performing the surgical abortion procedure (SAB) examined the products of conception prior to the patient discharge. Review of the medical record revealed documentation of examination of the POC completed by the technician.

Interview with the Clinic Manager on 05/13/2015 at 1605 revealed there was no documentation available the physician performed an examination

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 11	E 158		

of the POC. The interview revealed the technician performs the examination of the POC. The interview revealed the physician only examines the POC if asked by the technician. The interview revealed the technician performing the examination of the POC was the standard of practice for the clinic.

Interview with Physician #1 on /2015 at 1040 revealed he performs abortion procedures at the clinic. The interview revealed he was the physician performing SABs today in the clinic. The interview revealed he does not examine the POC unless he is asked to do so by the Medical Technician (MT). The physician's signature on the form in the medical record means the MT told him of the examination conducted by the MT.

Interview with Medical Assistant #1 (MA) on 05/14/2015 at 0900 revealed the physician "sometimes" will check the POC. The interview revealed there is documentation of the gross exams and it is signed at the end of the day. The interview revealed she did not know when the physician signed it.

Interview with MA #2 on 05/14/2015 at 0910 revealed she examines the POC after a SAB. The interview revealed the physician does not examine the POC. The interview revealed if she has a question regarding her examination of the POC she will ask another MA. The interview revealed she has never asked the physician about her examination of the POC. The interview revealed "Sometimes" the physician may come into the room where the examination of the POC is done. The physician may check the POC.

Interview with MA #3 on 05/14/2015 at 0925 revealed she examines the POC. The interview

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	05/14/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 12 revealed she examines for fetal parts, sac and chorionic villi. The interview revealed if she has a concern she will ask the physician to check the POC. The interview revealed she will tell the physician her exam results.	E 158		

Tag E 132: I have revised A Woman's Choice of Raleigh Policy and Procedure manual to include selection and exclusion of patients. The Protocol for patients that cannot be seen at our facility will be as follows; to refer patient to their Primary Care Physician or UNC for care and or abortion. Patients not within range to have abortion at our facility will be given information on adoption, continuing pregnancy and/or referral to Atlanta Women's Center in Atlanta GA. This policy will be implemented by all staff members responsible for giving information on adoption, continuing pregnancy and or referral to Atlanta Women's Center. A written policy has been added to AWCR policy and procedure manual as of 6/2015. See attachment 1

Tag E 136: A Woman's Choice of Raleigh staff member will provide each patient with the following prior to obtaining the consent for surgery as required by Rule .0305, (1) Fee schedule (2) the name of attending physician and a statement advising physician has no admitting privileges. (3) Instruction for post-procedure emergency (4) Grievance procedure a patient may follow if dissatisfied with care or services. (5) The telephone number of complaints Investigation branch of the division. A Woman's Choice of Raleigh has updated Patient Rights Document which includes telephone number to AWCR, AWCR Corporate Office and The City of Raleigh Department of Health if grievance/complaint shall arise. This document will be given to every patient and advised of document during counseling session by responsible staff member. This system has been revised and will be implemented no later than 7/13/2015. See attachment 2

Tag E 137: A Woman's Choice of Raleigh has revised patients permanent record to include date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnosis; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witness; voluntarily-signed consent for each surgery or procedure and physician's signature performing the procedure; and the physician's authenticated history and physical examination including identification of pre-existing or current illnesses, drug sensitivities, or other idiosyncrasies having bearing on the operative procedure or anesthetic to be administered. All staff member will be responsible for reviewing patient records and assuring all parts are filled out to its entirety which includes, date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnosis; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witness; voluntarily-signed consent for each surgery or procedure and physician's signature performing the procedure; and the physician's authenticated history and physical examination. Physical Exam documentation will be handwritten until charts are reprinted. This system has been revised and updated and will be implemented no later than 7/13/2015. See Attachment 3

Tag E 158: A Woman's Choice of Raleigh has revised our Products of Conception Examination Policy to state that (1) The physician performing the abortion is responsible for examination of all P.O.C prior to patient discharge. Examination shall note specifically the presence or absence of chronic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) The facility shall have a written procedures, supplies and equipment available for gross and

microscopic evaluation of abortion specimens. In cases where microscopic examination is negative for chronic villi and fetal parts, or the weight of the P.O.C falls substantially below appropriate weight range

Tag E 158: Continued from page 1

for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C (3) The results of this examination, findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record. (4) The facility shall establish procedures for obtaining, identifying, storing and transporting specimens. (5) The facility shall establish a method for follow-up of patients on whom no villi are seen. The pathologist will insure the physician is performing physical examination and documentation of P.O.C prior to patient discharge. This system has been revised and being implemented as of 5/2015. See Attachment 4

Attachment 1

Declined/Referred Patients Policy

Patients that cannot be seen at our facility for medical reasons such as; hypertension, anemia, or any other medical condition will be referred to their Primary Care Physician. If the patient does not have PCP we refer patients to UNC Hospital for care and or abortion. Patients that are not within range to have abortion at our facility are given information on adoption, continuing pregnancy and/or referral to Atlanta Women's Center in Atlanta Georgia. 1 404-257-0057

Attachment 2

A WOMAN'S CHOICE OF RALEIGH PATIENT RIGHTS DOCUMENT

Patients have a right to:

- Reasonable access to care, treatment or service and that her rights are respected and supported.
- Be informed about and participate in decisions regarding care.
- Consent for or refusal of treatment to the extent permitted by law, after a clear explanation of risks, benefits and alternative treatments has been provided.
- Make decisions or be informed about restriction of companions, telephone calls in the clinic.
- The appropriate assessment and management of pain.
- Security and safety, personal privacy, and confidentiality of information. Patient information is limited to those individuals designated by law, regulation, and policy of duly authorized as having a need to know or granting of permission by patient.
- Have a family member or her own physician notified of admission to a hospital in an emergency.
- The identity of those providing care to her.
- Review of and access to the medical record within a reasonable time frame.
- Freedom from physical, mental, emotional, verbal, sexual, or psychological abuse, neglect corporal punishment.
- Clearly presented and understood medical information regarding patient's condition, diagnosis and treatment.
- To be informed, when appropriate, about the outcomes of care, including unanticipated outcomes.
- Voice concerns to clinic or medical staff without fear of reprisal or discrimination.

In the Interest of always trying to improve our service and patient care, you can contact management at the following numbers with any concerns or complaints:

A Woman's Choice of Raleigh: 1 800-540-5690
A Woman's Choice of Raleigh Corporate office: 1 800-298-8874 or 904 448-8877
The City of Raleigh Department of Health 1 800-624-3004 or 919 855-4500

attachment 3

CONSENT TO ULTRASOUND EXAMINATION

I request an abdominal ultrasound gestational dating examination by *A Woman's Choice of Raleigh, Inc.*. The purpose of this exam is to verify and date a pregnancy. I understand that no further conclusions will be made based on the ultrasound performed here. The ultrasound performed today will not be used to identify gender, diagnose fetal anomalies, or rule out ectopic pregnancy. I am aware that I can elect to receive more extensive ultrasound examinations from providers outside of *A Woman's Choice of Raleigh, Inc.*, but it is my responsibility to find the provider and schedule the appointment if so desired. I have been informed that findings related to the ultrasound are subject to a plus/minus variation of 10 to 14 days.

Patient Signature **Date**

CONSENT TO ABORTION PROCEDURE DURING FIRST TWENTY WEEKS OF PREGNANCY

This consent is executed to me on the date indicated for the purpose of inducing the named physician to perform a medical procedure and prescribe medications in order to terminate my pregnancy, which treatment is to be performed at *A Woman's Choice of Raleigh, Inc.* in Raleigh, NC. (The physicians name is located on the procedure form of this chart.) In order to induce the physician to perform the procedure and to further induce *A Woman's Choice of Raleigh, Inc.* to permit the procedure to be performed, I hereby state the following:

My name is _____, I am _____ years of age, and I am of sound mind. I represent that my medical history is accurate, including medical conditions, use of medications, and use of any illicit drugs or alcohol. I understand withholding information regarding my medical history could be life threatening. I also understand that the physician(s) treating me are NOT RESPONSIBLE for complications resulting from information I withhold. I hereby consent to my physician to terminate my pregnancy by elective abortion at *A Woman's Choice of Raleigh, Inc.*

The nature and purpose of the abortion, methods of treatment, alternative procedures which, in the opinion of my physician, might be appropriate and advantageous, the risks attendant to the treatment, the potential complications and harmful side effects, and all other pertinent factors have been fully discussed and explained to me.

I have received information and counseling regarding alternatives to abortion, the procedure to be performed, and currently available methods of birth control.

I realize that abortions by D&E (dilation and evacuation) occasionally have associated complications, and that I am financially responsible for any complications requiring further medical care. I understand that the complications associated with an abortion are generally less severe than those associated with childbirth. Nonetheless, I realize that there are risks of minor and major complications that may occur in this procedure as in any surgical procedure. I understand the possibility of the following complications, and that I may need to be hospitalized for the investigation and/or treatment of: 1) Perforation of the uterus – a hole in the uterus which may require hospitalization for major surgery that may include removal of the uterus; 2) Perforation of a major pelvic vessel – this would require immediate hospitalization; 3) Infection – which can require antibiotics or surgical treatment; 4) Excessive bleeding – which may require medication, transfusion, or surgery (including hysterectomy); 5) Incomplete termination of pregnancy – which may require a second operative procedure; 6) Pain and cramps – which may be severe; 7) Adverse reactions to medications or anesthesia; 8) Asherman's Syndrome – scar tissue in the uterus which may lead to infertility or may necessitate surgery; 9) Perforation of the bowel/bladder – a hole in the bowel/bladder which may require surgery to repair; 10) Death; 11) Medical problems – i.e. embolism, anemia, cardiac problems, depression, etc.

In the event that any of the aforementioned complications occur, or any complications occur after I leave the premises, I certify that I will immediately advise my physician at *A Woman's Choice of Raleigh, Inc.* so that remedial or follow-up advise, care, or treatment can be instituted.

I acknowledge that I have been informed about the necessity of a post-operative follow-up two to three weeks following the procedure. I have been advised to have this exam with *A Woman's Choice of Raleigh, Inc.*. If I choose to have this very important exam elsewhere, I promise to inform *A Woman's Choice of Raleigh, Inc.* of subsequent clearance by another physician of any post-operative problems or failure to return for my follow-up appointment relieves the operating physician, *A Woman's Choice of Raleigh, Inc.*, their associates, and agents from any responsibility for medical problems or consequences that could arise as a result of my failure to return to this office.

_____ Medications I receive from *A Woman's Choice of Raleigh, Inc.* may or may NOT come in a child-proof container. I understand that if I need a child-proof container, one may be obtained from any pharmacy.

_____ I have been advised not to drive myself from the facility after my procedure. I understand that I may receive medications that affect my ability to drive, operate machinery or decision making for 24 hours after discharge.

For patients with Rh negative blood type only:

It is preferable that all non-sensitized Rh negative women be inoculated with an adequate dose of Rh immune globulin immediately following an induced abortion. It is the policy of *A Woman's Choice of Raleigh, Inc.* to administer this injection to all Rh negative patients

_____ I have received information concerning Rh negative blood and consent to the administration of Rh immune globulin.

_____ I decline the administration of Rh immune globulin injection. I fully understand the risk involved to my future pregnancies by refusing this injection.

Patient Signature **Parent/Guardian Signature** **Date**

Witness **Date** _____, **M.D.**

COUNSELOR'S STATEMENT

_____ I have reviewed and given patient information on the following: "Counseling for Abortion", D&E Patient Counseling; "Post Abortion Instructions" and "Contraceptive Counseling".

_____ I have confirmed that patient is satisfied with her decision to terminate her pregnancy. Patient stated she understands D&E procedure as well as risks and complications associated with the procedure

_____ Patient has been adequately informed of the D&E procedure, her questions have been answered to the best of my ability, and the consent form has been signed.

_____ The patient remains that this decision is of her own free will.

Counselor's/RN **Date**

attachment 3

PROCEDURE FORM

Surgeon: _____, **M.D.** **Assistant in OR:** _____

PELVIC EXAM (Check Indicates WNL) Physical Exam Y N

Cervix:_____ Uterus:_____ Size:_____ Adnexa:_____

OPERATIVE NOTE

Pre-Operative Diagnosis: Intrauterine Pregnancy, _____ weeks gestation.
Post-Operative Diagnosis: Intrauterine Pregnancy, _____ weeks gestation.
Operation: Dilation and Evacuation
Anesthesia: Paracervical Block
Procedure Time: _____ to _____

The patient was placed in the dorsal lithotomy position, examined, and prepped. The uterus position was _____and consistent with _____ weeks gestation. The cervix was cleansed with betadine or alternative solution. A Paracervical block was performed with _____ cc of 1% lidocaine. The anterior lip of the cervix was grasped with a single-toothed tenaculum and the cervical canal was dilated to a _____ Pratt dilator. Evacuation of the uterine contents was performed used a _____ mm suction curette. The uterus was / was not explored with forceps / sharp curette. The procedure being terminated, the patient was taken to the recovery room in satisfactory condition.

Additional Anesthesia: _____ N_2O, Self-inhalation/ _____ IV Sedation (_____mcg Fentanyl, _____mg Versed) Time:_____

Time	O_2 Saturation	Pulse	Respirations	LOC

Procedure was done under ultrasound guidance Y or N
IV fluids administered (_____cc Lactated Ringers) Y or N
_____ Oxytocin 10u IM or IV
_____ Ergonovine 0.2mg IC or IM

Estimated Blood Loss _____ Complications Y or N _____

_____, **M.D.**

GROSS DESCRIPTION REPORT

Gross description:
The tissue was submitted in a container identified as products of conception. _____ grams of tissue are persent and gross appearance reveals products of conception (consistent / not consistent with _____ weeks gestation. Fetus (was / was not) intact.

_____ Chorionic villi seen
_____C,S.E x 4
_____ Sac seen
_____ Tissue forwarded for microscopic exam by pathologist.

Gross Description Identified By: _____ _____, M.D.

ORDERS

Pre-Op

1. Ibuprofen 800mg p.o. _____
2. Diazepam 5mg p.o. _____
3. Misoprostol 400mcg p.o. _____
4. Amoxicillin 2 grams p.o. _____
5. _____

Post-Op

1. Misoprostol 200mcg _____
2. Metronidazole 500mg p.o. x1 _____
3. Ergonovine 0.2mg (p.o. /IM) _____
4. Bay Rho-D IM (mini/full) _____
5. Ibuprofen 800mg p.o / Tylenol #3 w/codeine 300mg/30mg

V.O. _____, M.D.

Attachment 4

Product of Conception Examination Procedure

The POC from each surgical abortion procedure is to be examined by Physician and Pathologist for presence or absence of pregnancy tissue prior to the patient leaving the building. The following is the procedure for this examination.

1. The specimen will be in placed on the lab counter. Early pregnancies will still be in the sock and later pregnancies may remain in the Berkley jar.
2. Using ring forceps, strip the pregnancy tissue from the sock into the strainer.
3. Rinse the specimen thoroughly in tap water. Remove as much blood and clots as possible.
4. Swirl the tissue in the strainer to roll into a ball- place the tissue in a weighing container.
5. Weigh the specimen and container- be certain to record the weight of the empty container so it can be subtracted from the total.
6. Place the specimen in a pyrex type dish in approximately 1" of tap water.
7. Place the dish on top of the "back light" for visual examination.
8. Gently explore the contents of the dish to identify pregnancy tissue.
9. Record results on lab log.
10. Be certain to write "sac seen" when the gestational sac is clearly visible- especially in early pregnancies.
11. Label the dish with the patient's name so the physician can check contents.
12. If ample loose villi and/or a gestational sac are not visible on initial inspection, do the following: 1. Check the strainer for material stuck to mesh or 2. Invert the sock and rinse it through the water in your dish
13. If there is still an absence of villi and sac, notify the physician and clinic administrator.
14. Keep the specimen in the dish until the physician has determined her/his course of action.
15. Prepare specimen for transport to lab for microscopic examination.
16. Document your findings in the patient's chart and have your entry countersigned by the physician.
17. All specimens with appropriate findings are contained for proper disposal.
18. If you find any unusual structures, hydropic (enlarged) villi, or multiple pregnancies, have the physician examine entire specimen.

Revised 5/2015

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

CERTIFIED MAIL

NOTICE OF ADMINISTRATIVE ACTION
ABORTION CERTIFICATE

TO: **Allan Ross, MD, CEO**
Piedmont Carolina Medical Clinic
2425 Randleman Road
Greensboro, NC

FROM: **Azzie Y. Conley, RN**
Section Chief
Acute and Home Care Licensure and Certification Section

SUBJECT: **Provisional License to Operate**
Certificate No. AB 0015

FID No. 943400

DATE: **June 6, 2014**

Based on our review, we conclude **Piedmont Carolina Medical Clinic**, an abortion clinic has failed to substantially comply with the provisions of G.S. § 14-45.1(a) and G.S. §143B-10, the rules governing the certification for the performance of abortions. Therefore, the Department of Health and Human Services amends the certification for the above referenced abortion clinic. This amendment is based on the facility's failure to comply with the following:

PROVISIONAL CERTIFICATE

The facts upon which the certificate is amended are set out in the May 7, 2014 through May 9, 2014 Statement of Deficiencies which is incorporated by reference as though fully set out herein. The rule citations include:

10 NCAC 14E .0302	Person in Authority
10 NCAC 14E .0306(b)	Personnel Records
10 NCAC 14E .0306(e)	Personnel Records
10 NCAC 14E .0307(a)	Nursing Services
10 NCAC 14E .0312(a)	Medications and Anesthesia

The effective date of the Provisional Certificate is May 9, 2014. The Provisional Certificate will remain in effect until such time it is determined the facility is in compliance with the rules. The new certificate should be posted in a public area. The previously issued certificate **(2014)** must be returned to this office.

APPEAL NOTICE

You have the right to contest this provisional certificate by filing a petition for a contested case hearing with the Office of Administrative Hearings (OAH) within sixty (60) days of your receipt of this letter. For complete instructions on the filing of petitions, please contact OAH at (919) 733-2698. The mailing address for OAH is as follows:

Office of Administrative Hearing
6714 Mail Services Center
Raleigh, NC 27699-6714

N.C.G.S. § 150B-23 provides that you must also serve a copy of the petition on all other parties, which includes DHHS. The Department's representative for such actions is Ms. Emery Edwards Milliken, General Counsel. This person may receive service of process by mail at the following address:

Ms. Emery Edwards Milliken, General Counsel
NC Department of Health and Human Services
Office of Legal Affairs
2005 Mail Service Center
Raleigh, NC 27699-2005

If you do not file a petition within the sixty (60) day period, you will lose your right to appeal and the action explained in this letter will become effective as described above. In addition to your right to file a petition for a contested case hearing, N.C. Gen. Stat. § 150B-22 encourages the settlement of disputes through informal procedures. In keeping with this law, this office remains readily available for discussion or other informal procedures to assist in resolving any dispute you may have with our findings and action. Please note that the use of informal procedures does not extend the sixty (60) days allowed to file for a contested case hearing as explained above.

Should you have any questions regarding any aspect of this letter, please do not hesitate to contact me at the Department of Health and Human Services, Division of Facility Services, Acute and Home Care Licensure and Certification Section, 2712 Mail Service Center, Raleigh, North Carolina 27699-2712 or contact me at (919) 855-4646.

cc: Drexdal Pratt, Director, Division of Facility Services
Cheryl Quimet, COO, Division of Facility Services
Emery Edwards Milliken, General Counsel, Department of Health and Human Services
File

Division of Health Service Regulation

REC'D AUG 0 6 2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

db 8/8/14 approved

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 131	.0302 PERSON IN AUTHORITY 10A NCAC 14E .0302 Person in Authority The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic. This Rule is not met as evidenced by: Based on observation, nursing staffing schedules review, procedure log review and staff and physician interviews, the facility's governing authority failed to provide oversight of nursing functions by failing to ensure there was one registered nurse (RN) on duty in the clinic at all times when patients are in the facility and failing to obtain a physician's order for medications administered. The findings include: 1. The facility failed to ensure there was one registered nurse (RN) on duty in the clinic at all times when patients are in the facility for 59 of 97 procedure days. ~ cross refer to 10A NCAC 14E .0307 Nursing Service 2. The facility staff failed to obtain a written physicians order for medications administered for 3 of 20 patient records reviewed (#2, 3, 14) ~ cross refer to 10A NCAC 14E .0312 Medications and Anesthesia	E 131	E131 The medical director will be the person of authority to monitor the administrative and professional functions of the clinic. This has been corrected. A RN is now scheduled and will be present on all procedure days and will be present. Staff has been informed that if RN is not available procedures are not to be performed. We will supply what ever documentation the State requires to confirm this is occurring. Receptionist will be responsible for making schedule for RNs and keeping these records for review and monitoring by the State. Schedules and time sheet will be keep by the office manager. Medical director shall be responsible for insuring that procedures are not performed if RN is not available and will audit these records monthly to insure compliance. Pre operative orders will be prepared by the medical director and signed by physicians working at the clinic. This has been completed as of June 1, 2014	6/1/2014
E 147	.0306(B) PERSONNEL RECORDS 10A-14E .0306 (b) Job Descriptions: (1) The facility shall have a written description which describes the duties	E 147		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 147	Continued From page 1 of every position. (2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required. (3) The facility shall review annually and update all job descriptions, and shall provide a current copy to each employee or contractual employee assigned to the position. This Rule is not met as evidenced by: Based on personnel file review and staff interview the facility failed to review annually and update all job descriptions in 5 of 5 employees personnel records reviewed (#1, #2, #3, #4 and #5). The findings include: 1. Personnel file review of RN staff #1 revealed the staff member was a registered nurse and had worked at the facility since 1992. Review of job descriptions located in RN staff #1's personnel file included the following: Counselor and Recovery Room Nurse. Review of the job descriptions revealed no documentation of an annual review of the job descriptions. File review revealed the last annual evaluation and review of the job descriptions was in 2012. Interview with administrative staff on 05/09/2014 at 1640 revealed there was no documentation available of an annual review of the job descriptions. 2. Personnel file review of RN staff #2 revealed the staff member was a registered nurse and had	E 147	E147 The Medical Director is responsible for review of all job descriptions and for insuring that these are reviewed annually and keep up to date. Annual evaluations of personnel will be done and completed by September 1 of each year. These will be keep on file for review. LPN will prepare and keep these files up to date for review by the medical director. A review and updating is now under way of every job at the clinic. The update will include job descriptions listing,qualifications, education,training,experience, special abilities and licenses or certifications required. This has been completed as 7/15/2014	7/15/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 147	Continued From page 2 worked at the facility since 1989. Review of job descriptions located in RN staff #2's personnel file included the following: Counselor and Recovery Room Nurse. Review of the job descriptions revealed no documentation of an annual review of the job descriptions. File review revealed the last annual evaluation and review of the job descriptions was in 2012. Interview with administrative staff on 05/09/2014 at 1640 revealed there was no documentation available of an annual review of the job descriptions. 3. Personnel file review of lab staff #3 revealed the staff member was a Lab Technician and had worked at the facility since 2000. Review of job descriptions located in lab staff #3's personnel file included the following: Lab Technician. Review of the job description revealed no documentation of an annual review of the job description. File review revealed the last annual evaluation and review of the job description was in 2012. Interview with administrative staff on 05/09/2014 at 1640 revealed there was no documentation available of an annual review of the job descriptions. 4. Personnel file review of LPN staff #4 revealed the staff member was a licensed practical nurse and had worked at the facility since August 1977. Review of job descriptions located in LPN staff #4's personnel file included the following: receptionist, counselor, lab technician, sterilization technician, procedure room nurse and recovery room nurse. Review of the job descriptions revealed no documentation of an annual review of the job descriptions. File review revealed the last annual review of the job	E 147	See above	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 147	Continued From page 3 descriptions was 2012. Interview with administrative staff on 05/09/2014 at 1640 revealed there was no documentation available of an annual review of the job descriptions. 5. Personnel file review of administrative staff #5 revealed the staff member was an administrative staff member. Review of job descriptions located in administrative staff #5's personnel file included the following: receptionist, procedure room nurse, environmental technician and management. Review of the job descriptions revealed no documentation of an annual review of the job descriptions. File review revealed the last annual review of the job descriptions was 2012. Interview with administrative staff on 05/09/2014 at 1640 revealed there was no documentation available of an annual review of the job description.	E 147	See above E 150. The Medical Director is responsible for insuring that health records are up to date and in compliance with State and local regulations. LPN shall be responsible for collecting and filing such records for review by the Medical Director and State. This will be reviewed on annual basis by the Medical Director by September 1 annually.	7/15/2014
E 150	.0306(E) PERSONNEL RECORDS 10A-14E .0306 (e) Employee and contractual employee records for health screening, education, training and verification of professional certification shall be available for review by the Division. This Rule is not met as evidenced by: Based on personnel file review and staff interview the facility failed to obtain annual TB status assessment for 2 of 5 employees reviewed. The findings include:	E 150		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 150	Continued From page 4 1. Personnel file review of RN staff #2 revealed the staff member was a registered nurse and had worked at the facility since 1989. Review of health record did not reveal a TB assessment or TB test for 2013. Review revealed the last assessment was in February 2012. Interview with administrative staff on 05/09/2014 at 1640 revealed there was no documentation of TB assessment after 2012 available. Interview revealed RN staff #2 works at another facility and the assessment would have been done there, but confirmed the documentation was not available in the facility's personnel file. 2. Personnel file review of lab staff #3 revealed the staff member was a Lab Technician. Review of health record revealed lab staff #3 had previously had a positive TB skin test result and subsequently needed assessment and potentially chest xray. Review revealed the last TB assessment documented was in October 2012. Interview with administrative staff on 05/09/2014 at 1640 confirmed there was no TB assessment completed for lab staff #3 after 2012.	E 150	A data base has been created for confirmation of TB testing as required. All employees required to have TB testing have been instructed to bring in these test results immediately so they can be placed in there files as well as the master file. All employees who job requires a license or certification have been asked to provide their current certificates immediately if they are not in our possession and these will be keep in the employee's file. The LPN will be responsible for collecting *and holding these records* for annual review by the Medical Director This has been completed on 7/15/2014 and reviewed annually by the Medical Director on or before September 1 each year.	
E 151	.0307 NURSING SERVICE 10A-14E .0307 (a) There shall be a minimum of one registered nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times when patients are in the facility. (b) There shall be supporting personnel sufficient to meet patient	E 151	E151 The Medical Director is responsible for insuring that a RN is present on all procedure days. He has communicated to staff that no procedures are to be performed without RN present on site.	6/1/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 5 needs and to provide safe patient care. This Rule is not met as evidenced by: Based on observation, nursing staffing schedules review, procedure log review and staff and physician interviews, the facility failed to ensure there was one registered nurse (RN) on duty in the clinic at all times when patients are in the facility for 59 of 97 procedure days. The findings include: Interview on 05/07/2014 at 1030 with LPN staff #4 revealed the facility scheduled abortion procedures on Monday afternoon, Thursday morning, Friday afternoon and Saturday morning. Interview on 05/08/2014 at 1055 with LPN staff #4 revealed there was no registered nurse working in the clinic on 05/08/2014. Interview revealed the registered nurse that was scheduled for 05/08/2014 had called out that morning around 0855 due to a conflict with another job. Interview with the staff member revealed she was unable to get another registered nurse to replace her. The staff member stated "It happens from time to time. (The physician) is going to watch over the recovery room and do procedures." Observation on 05/08/2014 at 1135 revealed the following staff working in the clinic on 05/08/2014: Physician A, administrative staff #5 (office manager), LPN staff #4 (LPN), LPN staff #6 (LPN) and lab staff #3 (Lab technician). Observation at 1135 revealed Physician A was in the procedure room with LPN staff #6 and Patient #34 who was having a surgical abortion procedure. LPN staff #4 was in the recovery room with two patients (#36 and #35). Administrative	E 151	Receptionist is responsible for making out the RN schedules and keeping these records as well as time sheets so as to confirm that an RN has been present on procedure days. Procedures are to be canceled and rescheduled if RN is not present. Staff has been informed at there will be no exceptions to this rule. Medical Director will do weekly reviews to insure compliance. This has been completed.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 6 staff #5 was in the front office reception area giving post procedure instructions to a patient that had just had a surgical procedure completed. Lab staff #3 (lab technician) had already left the clinic for the day. Patient #31 was sitting outside the lab area waiting to go to the procedure room for her surgical procedure. Observation at 1140 revealed Physician A came out of the procedure room, washed his hands in the sink and immediately entered another procedure room where patient #31 had been moved. At 1145 LPN staff #6 brought Patient #34 into the recovery room (now three patients in the recovery room with LPN staff member #4). Observation revealed LPN staff #6 left the clinic at 1151 after all the procedures for the day had been completed. Observation revealed Physician A left the clinic at 1212. Observation at 1212 revealed three patients remained in the recovery room with LPN staff #4. Observation revealed the last patient (#31) left the clinic at 1240 (33 minutes after Physician A left the clinic). Review of the procedure log for 05/08/2014 revealed a total of six surgical abortion procedures were performed on 05/08/2014. Interview on 05/08/2014 at 1205 with Physician A revealed he was made aware around 1030 that there was no registered nurse in the clinic. The physician stated "I was here to supervise the LPNs and I am immediately available." The physician explained that the surgical procedures normally lasted from two to seven minutes and he could be available in the recovery room if needed. The physician stated "If there were complications, I would take care of it. I don't think I was putting patients at risk today. An RN would not have made a difference. I felt patients were safe, absolutely. I have surgery scheduled at 1230. I	E 151	See above	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 7 need to leave." Telephone interview on 05/08/2014 at 1224 with Physician B revealed he was the owner of the clinic. Interview revealed the physician had not been made aware of the failure to have a registered nurse (RN) on 05/08/2014 until the surveyor asked to speak with him. Physician B stated "Sometimes we have difficulty getting RNs, especially on Thursdays." The physician stated he always stayed until all the patients had left the clinic. The interview revealed the RNs had full time jobs and it was difficult getting RNs into the clinic because of the conflict with their other jobs. Physician B stated "I understand that we have a problem on Thursday. It has been going on at least six months. It is a chronic problem.... I know it is a problem. I will fix it. We just won't have procedures when there is no nurse here. I know it is a requirement." Telephone interview on 05/08/2014 at 1248 with RN staff #2 revealed she is a registered nurse and was scheduled to work at the facility on 05/08/2014. Interview with the nurse revealed she works at a local hospital in a management role and is "always on call." Interview revealed the nurse was called to work at the hospital and unable to work at the facility today (05/08/2014). The nurse stated she called in around 0900 to report that would not be in to work at the facility. The nurse stated she normally worked at the facility every other Thursday and this was the "first time that I can recall calling in." Review of facility staff work schedules from November 1, 2013 through May 9, 2014 revealed there was no RN on the premises on the following dates: November 4, 7, 9, 11, 14, 18, 21 and 25, 2013 (eight days); December 2, 5, 9, 12, 13, 14,	E 151	See above	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 8 16, 19, 21, 23, 27, 28, and 30, 2013 (thirteen days); January 6, 9, 13, 16, 20, 23, 25, 27 and 30, 2014 (nine days); February 1, 3, 6, 8, 10, 17, 20, 24 and 27, 2014 (nine days); March 3, 6, 10, 13, 17, 20, 24, and 27, 2014 (eight days); April 3, 7, 10, 12, 17, 18, 24, 25 and 28, 2014 (nine days); and May 1, 5 and 8, 2014 (three days). Review of daily procedure logs from November 1,2013 through May 9, 2014 revealed a total of sixteen procedure days in November 2013; sixteen procedure days in December; seventeen procedure days in January 2014; fifteen procedure days in February; sixteen procedure days in March; twelve procedure days in April; and five procedure days in May. Review of the daily procedure logs revealed surgical abortion procedures were conducted on the following dates: November 4, 7, 9, 11, 14, 18, 21 and 25, 2013; December 2, 5, 9, 12, 13, 14, 16, 19, 21, 23, 27, 28, and 30, 2013; January 6, 9, 13, 16, 20, 23, 25, 27 and 30, 2014; February 1, 3, 6, 8, 10, 17, 20, 24 and 27, 2014; March 3, 6, 10, 13, 17, 20, 24, and 27, 2014; April 3, 7, 10, 12, 17, 18, 24, 25 and 28, 2014; and May 1, 5 and 8, 2014. The review revealed there was no registered nurse in the facility when procedures were occurring on 8 of 16 procedure days in November 2013; 13 of 16 procedure days in December 2013; 9 of 17 procedure days in January 2014; 9 of 15 procedure days in February 2014; 8 of 16 procedure days in March 2014; 9 of 12 procedure days in April 2014; and 3 of 5 procedure days in May, 2014 for a cumulative total of 59 of 97 (61%) procedure days without a registered nurse in the facility. Interview on 05/08/2014 at 1530 with	E 151	See above	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 9 administrative staff #5 revealed she coordinates the staff work schedules. The staff member stated she makes the calendar out about a week prior to the procedures the following week. The staff member stated she writes down the staff names on the calendar. Interview revealed RN staff #7 (RN) works on Fridays and RN staff #1 works on Saturdays. Interview revealed RN staff #2 was called on 05/07/2014 to work on 05/08/2014. Interview revealed she has only had one day (March 31, 2014) in the past six months that she had an RN scheduled to work on a Monday or Thursday. The staff member reviewed the staff work schedules and confirmed that there was no RN on the premises for 59 of 97 days when procedures were completed at the facility.	E 151	See above	
E 159	.0312(A) MEDICATIONS AND ANESTHESIA 10A-14E .0312 (a) Medication (1) No medication or treatment shall be given except on written order of a physician. (2) Medications must be administered in accordance with the Nurse Practice Act of the State of North Carolina, and must be recorded in the patient's permanent record. This Rule is not met as evidenced by: Based on closed medical record review and staff and physician interviews, the facility staff failed to obtain a written physicians order for medications administered for 3 of 20 patient records reviewed (#2, 3, 14) The findings include:	E 159	E159 The Medical Director is the responsible party for preparing pre and post op orders. Pre operative orders have been created to insure patient's do not receive any medications without a physician's order. All pre and post op orders are to be signed by the ordering physician. This will be reviewed weekly by LPN to insure all orders have MD signatures.	7/1/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 159	Continued From page 10 1. Review of the clinic record of Patient #14 revealed a year-old female presented to the clinic on 2014 for a surgical abortion. The review revealed an ultrasound which showed she was "too early" and the plan was for the patient to return later. Review revealed "Cipro 500 mg (1) po (by mouth)" and "Naproxen 500 mg (1) po" were administered at 0900 by LPN staff #4. The review further revealed a blank "Doctor's Post-Op Orders" sheet; no written order for medications and no physician signature. Interview with LPN staff #4 revealed these medications are routinely given to everyone and physicians write the order at the time of the procedure. Interview revealed the patient did not have the procedure so the written orders were not done. Further interview revealed there was no written standing order for these two medications to be administered pre-procedure. Interview with Physician A on 05/08/2014 at 1015 am revealed "there is a standing order for pre-op meds. Every patient gets them." Further interview revealed the standing order "may not be in writing" and "we sign these at the time of the procedure." Continued interview acknowledged an understanding that "we need to have a written order" before medications are administered. 2. Review of the clinic record of Patient #3 revealed a 29 year old female presented to the clinic on /2014 for a medical abortion. Review revealed LPN staff #4 administered "Cipro 500 mg (1) po" and "Naproxen 500 mg 1 po" at 0955. Review revealed the Physician order sheet was left blank, there were no written orders for the two medications and there was no physician signature.	E 159	See above Education of Staff All changes to the policy and procedure manual for the clinic will be placed both in the main Policy and and Procedure Manual and in a separate note book in the recovery room that will be readily available to the staff for review on a monthly basis so as to educate the staff concerning any new changes in procedures, policies or job responsibilities. This note book will be entitled "Policy and Procedure Updates"	7/15/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	ab0015	A. BUILDING: _____ B. WING _____	05/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PIEDMONT-CAROLINA MEDICAL CLIN	2425 RANDLEMAN RD GREENSBORO, NC 27406

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 159	Continued From page 11 Interview with LPN staff #4 on 05/08/2014 at 1550 confirmed the patient received the medications and no written physician order was obtained. 3. Review of the clinic record of Patient #2 revealed a 22 year old female presented to the clinic on /2014 for a medical abortion and on /2104 for a follow-up surgical abortion. Review revealed the patient returned again on 03/06/2014 with a positive pregnancy test. Review revealed LPN staff #4 administered "Cipro 500 mg (1) po" and "Naproxen 500 mg 1 po" on 03/06/2014 at 0928. Review revealed an ultrasound was done and the physician determined the patient had "...complete abortion..." and therefore no procedure was performed. Further review failed to reveal a written physician's order for the medications administered. The "Doctor's Post-Op Orders" sheet was blank, with no written orders and no physician signature. Interview with LPN staff #4 on 05/09/2014 at 1500 confirmed the medications were administered to Patient #2. Interview revealed the patient returned with a planned procedure. Interview revealed the procedure was not done, but the medications were administered. Interview confirmed there was no written physician order for the medications. Continued interview revealed the process of medication administration changed on 05/09/2014 to give the medications after the procedure and after a written physician order is obtained.	E 159	See above	

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

June 23, 2015

Sandy St Clair, CEO
Carolina Women's Clinic
421 Wendover Road
Charlotte, NC 28211

Re: State Licensure Survey

Dear Ms St Clair,

Thank you and your staff for the assistance and cooperation extended during the state licensure survey at Carolina Women's Clinic in Charlotte, NC from June 15, 2015 through June 17, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina RulesGoverning the Certification of Clinics for Abortions . As discussed at the exit conference, state licensure deficiencies were identified with respect to 10A NCAC 14E .0304(d)(2) Admission and Discrarge, 10A NCAC 14E .0306(e) Personnel Records and 10A NCAC 14E .0307(a) Nursing Service.

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An *original* of the enclosed form CMS 2567, with the plan of correction added, must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time. A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Debbie McCarty,
Nurse Consultant Lead
Acute and Home Care Licensure and Certification Section

Enclosures: State Form - Statement of Deficiencies

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

7/10/15 OM

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	.0304(D) ADMISSIONS AND DISCHARGE 10A-14E .0304 (d) Following admission and prior to obtaining the consent for surgery required by Rule .0305(a) of this Section, representatives of the clinic's management shall provide to each patient the following information: (1) A fee schedule and any extra charges routinely applied, (2) The name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included; (3) Instructions for post-procedure emergencies as outlined in Rule .0313(d) of this Section; (4) Grievance procedures a patient may follow if dissatisfied with the care and services rendered; and (5) The telephone number of the Complaints Investigation Branch of the Division. This Rule is not met as evidenced by: Based on policy and procedure review, staff interview, credentialing file review and medical record reviews, the facility failed to notify patients prior to obtaining a consent for a procedure that the facility physician (MD #2), had no hospital admitting privileges in 6 of 20 medical records reviewed (Patients # 3, 10, 9, 13, 17 and 18). The findings include: Review of facility policies on 06/16/2015 revealed no policy or procedure regarding notification to patients prior to obtaining a consent for an abortion procedure that a facility physician that	E 136	Please see accompanying enclosed reply Dr	6/22/15

Received 6/30/15 mm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 1 was performing the procedure had no hospital admitting priviliges. Interview with Physician's Assistant (PA #3) on 06/16/2015 at 1430 revealed that no policy was available to ensure patients were notified that MD #2 did not have hospital admitting priviliges. Review of credentialing file for MD#2 revealed this physician had no hospital admitting privileges. Interview with PA #3 on 06/16/2015 at 1430 confirmed MD #2 had no hospital admitting priviliges. 1. Medical record review on 06/16/2015 for Patient #3 revealed a 21 year old female with a diagnosis of pregnancy of 10 weeks gestation. The patient was admitted for a surgical abortion (SAB) on /2015 at 0810 and discharged at 1210. The SAB began at 0948 and ended at 0954. The facility "Surgery Screening Sheet" is a patient signed form used to collect personal medical history, document information items provided and determine appointment date. The information item line which states:"our physicians have privileges at hospitals within 30 minutes of our facility that offer OB care" , {OB (pregnancy care)} was checked and the form signed by Patient #3. The Surgery Report form revealed that MD#2 without admitting privileges performed the SAB procedure. Interview with the PA #3 on 06/16/2015 at 1600 stated that the check mark indicated that the patient had been given the information checked and that no statement regarding MD #2's lack of admitting privileges was provided to the patient.	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 2 2. Medical record review on 06/16/2015 for Patient #10 revealed a 30 year old female with the diagnosis of pregnancy of 6 weeks 4 days gestation who was admitted to the facility for a SAB on 2015 at 1025 and was discharged at 1545. The facility "Surgery Screening Sheet" is a patient signed form used to collect personal medical history, document information items provided and determine appointment date. The information item line which states:"our physicians have privileges at hospitals within 30 minutes of our facility that offer OB care" , {OB (pregnancy care)} was checked and the form signed by Patient #10. The Surgery Report form indicated that MD #2 without admitting privileges performed the SAB procedure. Interview with PA #3 on 06/16/2015 at 1600 stated that the check mark indicated that the patient had been given the information checked and that no statement regarding MD #2's lack of admitting privileges was provided to the patient. 3. Medical record review on 06/16/2015 for Patient #9 revealed a 27 year old female with the diagnosis of pregnancy of 8 weeks 6 days gestation who was admitted to the facility for a SAB on /2015 and was discharged at 1415. The SAB began at 1310 and ended at 1315. The facility "Surgery Screening Sheet" is a patient signed form used to collect personal medical history, document information items provided and determine appointment date. The information item line which states:"our physicians have privileges at hospitals within 30 minutes of our facility that offer OB care" , {OB (pregnancy care)} was checked and the form signed by Patient #9. The Surgery Report form indicated that MD #2 without admitting privileges performed the SAB procedure.	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 3 Interview with PA #3 on 06/16/2015 at 1600 stated that the check mark indicated that the patient had been given the information checked and that no statement regarding MD #2's lack of admitting privileges was provided to the patient. 4. Medical record review on 06/16/2015 for Patient #13 revealed a 30 year old female with the diagnosis of pregnancy of 7 weeks gestation who was admitted to the facility for a Medical Abortion Procedure (MAB) on /2015 and was discharged at 1145. The facility "Medical AB Screening Sheet" is a patient signed form used to collect personal medical history, document information items provided and determine appointment date. The information item line which states:"our physicians have privileges at hospitals within 30 minutes of our facility that offer OB care" , {OB (pregnancy care)} was checked and the form signed by Patient #13. The Surgery Report form indicated that MD #2 without admitting privileges was the supervising physician on the MAB procedure. Interview with PA #3 on 06/16/2015 at 1600 stated that the check mark indicated that the patient had been given the information checked and that no statement regarding MD #2's lack of admitting privileges was provided to the patient. 5. Medical record review on 06/16/2015 for Patient #17 revealed a 28 year old female with the diagnosis of pregnancy of 6 weeks 5 days gestation who was admitted to the facility for a SAB on /2015 at 1245 and was discharged at 1700. The SAB began at 1550 and ended at 1557. The facility "Surgery Screening Sheet" (spanish version) is a patient signed form used to collect personal medical history, document	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 4 information items provided and determine appointment date. The information item line which states in spanish:"our physicians have privileges at hospitals within 30 minutes of our facility that offer OB care" , {OB (pregnancy care)} was checked and the form signed by Patient #17. The Surgery Report form indicated that MD #2 without admitting privileges performed the SAB procedure. Interview with PA #3 on 06/16/2015 at 1600 stated that the check mark indicated that the patient had been given the information checked and that no statement regarding MD #2's lack of admitting privileges was provided to the patient. 6. Medical record review on 06/16/2015 for Patient #18 revealed a 27 year old female with the diagnosis of pregnancy of 13 weeks 1 days gestation who was admitted to the facility for a SAB on /2015 at 0906 and was discharged at 1310. The SAB began at 1202 and ended at 1310. The facility "Surgery Screening Sheet" is a patient signed form used to collect personal medical history, document information items provided and determine appointment date. The information item line which states:"our physicians have privileges at hospitals within 30 minutes of our facility that offer OB care" , {OB (pregnancy care)} was checked and the form signed by Patient #18. The Surgery Report form indicated that MD #2 without admitting privileges performed the SAB procedure. Interview with PA #3 on 06/16/2015 at 1600 stated that the check mark indicated that the patient had been given the information checked and that no statement regarding MD #2's lack of admitting privileges was provided to the patient.	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 146	Continued From page 5	E 146		6/24/15 7/6/15
E 146	.0306(A) PERSONNEL RECORDS 10A-14E .0306 (a) Application. Each prospective employee or contractual employee must submit an application for employment which includes education, training, experience, and references. This Rule is not met as evidenced by: Based on personnel file review and staff interview, the facility failed to ensure a Licensed Practical Nurse (LPN #1) had a current, active license to practice as an LPN in North Carolina for 1 of 3 licensed staff reviewed. The findings include: Review of LPN #1's personnel file revealed the staff member had worked at the facility since November 23, 2013. Review of the LPN's job description revealed her job responsibilities included "Recovery Charge." Review of "Recovery Charge Duties" revealed "...4. Give post-op meds prescribed by MD and document time given, explaining to the patient the name and reason for the administration. ... " Review of LPN #1's personnel file revealed she had an active and current LPN license in a non-compact licensure State that expires on 01/31/2016. Review revealed there was no active and current LPN license available for the LPN to practice in North Carolina. Interview with PA #3 revealed LPN #1 did not have a current, active LPN license for North Carolina available. The PA stated she had checked the NC Board of Nursing and verified	E 146		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 146	Continued From page 6 there was no current LPN license in NC for LPN #1. Interview revealed the staff member had been working in a role as an LPN in the Recovery Room Charge position and administering medications.	E 146		7/8/15
E 151	.0307 NURSING SERVICE 10A-14E .0307 (a) There shall be a minimum of one registered nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times when patients are in the facility. (b) There shall be supporting personnel sufficient to meet patient needs and to provide safe patient care. This Rule is not met as evidenced by: Based on policy and procedure review, staff interview, staffing schedules, procedure log review and medical record reviews, the facility failed to ensure that one registered nurse (RN) who is currently licensed to practice professional nursing in North Carolina was on duty in the clinic when patients were present for 7 of 16 medical records reviewed (Patient #16, 15, 20, 3, 1, 4 and 9). The findings include: Review of facility policies on 06/16/2015 revealed no policy or procedure regarding ensuring the clinic was to be staffed with a registered nurse (RN) at all times while patients are in the facility.	E 151		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 7 Interview with PA #3 on 06/16/2015 at 1430 confirmed that no policy was available related to staffing the clinic with an RN at all times when patients are in the facility. Review of April through June 2015 staffing schedules revealed that on days in which a Physician Assistant (PA) was present in the facility, no RN was scheduled. Interview with PA #3 on 06/16/.2015 at 1430 confirmed that no RN was present when the PA was scheduled in the facility. Review of a surgical procedure log from 04/03/2015 through 6/17/2015, revealed 9 of 34 surgical procedure days were staffed with an RN. Dates included: 04/04/2015, 04/11/2015, 04/18/2015, 04/25/2015, 05/22/2015, 05/23/2015, 06/06/2015, 06/12/2015 and 06/13/2015. Review of the log revealed 25 remaining days when there was no RN present in the facility during procedures. Interview with the PA #3 on 06/16/2015 at 1430 confirmed that no RN had been staffed because a PA was scheduled. 1. Medical record review of Patient #16 revealed a 23 year old female with a diagnosis of pregnancy of 6 weeks gestation admitted on /2015 at 0808 for a surgical abortion procedure (SAB) and discharged at 1130. Chorionic villi and fetal parts weighing 10 grams were documented by the MD after the procedure. No complications were documented. Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by non-licensed staff. Review of the medical record	E 151		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued.From page 8 revealed no RN was present during Patient #16's encounter with this facility. The record revealed that non licensed staff (confirmed by the personnel record review) was assigned to the recovery charge role while the patient was in the recovery room. Record also revealed an Emergency Department (ED) visit occurred the next day which revealed an incomplete abortion (a possible outcome that each patient is advised of prior to the procedure and verified by a signed consent form in the medical record). Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was present in the facility during this encounter. 2. Medical record review of Pateint #15 revealed a 25 year old female with diagnosis of pregnancy of 6 weeks 6 days gestation admitted on /2015 at 0821 and discharged at 1210. A surgical abortion procedure (SAB) was performed with chorionic villi and fetal parts-10 grams were noted by medical doctor (MD). Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by non-licensed staff. Review of the medical record revealed no RN was present during Patient #15's encounter with this facility. The record revealed that non licensed staff (confirmed by the personnel record review) was assigned to the recovery charge role while the patient was in the recovery room. Record review revealed an Emergency Department (ED) visit occurred the next day which revealed an incomplete abortion (a possible outcome that each patient is advised of prior to the procedure and verified by a signed consent form in the medical record).	E 151		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 9 Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was present in the facility during this encounter. 3. Medical record review of Patient #20 revealed a 19 year old female with a diagnosis of pregnancy of 9 weeks gestation admitted on /2015 at 0930 for a SAB and was discharged at 1309. The MD noted the chorionic villi and fetal parts weighed 6 grams. Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by non-licensed staff. Review of the medical record revealed no RN was present during Patient #20's encounter with this facility. The record revealed that non licensed staff (confirmed by the personnel record review) was assigned to the recovery charge role while the patient was in the recovery room. Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was present in the facility during this encounter. 4. Medical record review of Patient #3 revealed a 22 year old female with a diagnosis of pregnancy of 10 weeks gestation admitted on /2015 at 0810 and discharged at 1210. A SAB was performed and the MD documented chorionic villi and fetal parts weighing 68 grams. No complications were noted. Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by non-licensed staff. Review of the medical record revealed no RN was present during Patient #3's encounter with this facility. The record revealed	E 151		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 10 that non licensed staff (confirmed by the personnel record review) was assigned to the recovery charge role while the patient was in the recovery room. Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was present in the facility during this encounter. 5. Medical record review of Patient #1 revealed a 35 year old female with a diagnosis of pregnancy of 14 weeks duration gestation admitted on /2015 for a SAB that began at 1206 and ended at 1213. Record review revealed the patient was discharged at 1313. Review revealed Chorionic villi and fetal parts weighing 19 grams were documented by the MD after the procedure. No complications were documented. Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by a non-licensed staff. Review of the medical record revealed no RN was present during Patient #1's encounter at this facility. The record revealed that non licensed staff was assigned to the recovery charge role while the patient was in the recovery room. Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was present in the facility during this encounter. 6. Medical record review of Patient #4 revealed a 23 year old female with a diagnosis of pregnancy of 14 weeks duration gestation admitted on /2015 for a SAB that began at 1141 and ended at 1146. Record review revealed the patient was discharged at 1246. Review revealed	E 151		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 11 Chorionic villi and fetal parts weighing 19 grams were documented by the MD after the procedure. No complications were documented. Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by a non-licensed staff. Review of the medical record revealed no RN was present during Patient #9's encounter at this facility. The record revealed that non licensed staff was assigned to the recovery charge role while the patient was in the recovery room. Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was present in the facility during this encounter. 7. Medical record review of Patient #9 revealed a 27 year old female with a diagnosis of pregnancy of 8 weeks, 6 days duration gestation admitted on /2015 for a SAB that began at 1310 and ended at 1317. Record review revealed the patient was discharged at 1415. Review revealed Chorionic villi and fetal parts weighing 54 grams were documented by the MD after the procedure. No complications were documented. Review of the Surgery Record form (used to document the recovery course of each patient and medications administered) revealed it was signed by a non-licensed staff. Review of the medical record revealed no RN was present during Patient #9's encounter at this facility. The record revealed that non licensed staff was assigned to the recovery charge role while the patient was in the recovery room. Interview on 06/16/2015 at 1630 with PA #3 revealed the PA was in the facility on the day of the procedure and confirmed that no RN was	E 151		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0004	A. BUILDING: _____ B. WING _____	06/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAROLINA WOMEN'S CLINIC	421 WENDOVER ROAD CHARLOTTE, NC 28211

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 151	Continued From page 12 present in the facility during this encounter.	E 151		

Carolina Center for Women
421 N. Wendover Rd.
Charlotte, NC 28211

Deficiency

E 136 0304 (D) Admission and Discharge

10A-14E (d) Following admission and prior to obtaining the consent for surgery required by Rule 0305(a) of this Section representatives of the clinic's management shall provide to each patient the following:
(2) The name of the attending physician and hospital admitting privileges, if any. In the absence of of admitting privileges a statement to that effect shall be included.

PROVIDER'S PLAN OF CORRECTION

The protocol for "Making Abortion Appointments Surgical and Medical" has been revised. The revision states all patients will be informed if the physician performing the procedure, either medical or surgical, does or does not have hospital admission privileges.

The "Surgery/Medical Appointment Screening Sheet" has been revised to include the ability to circle if the physician does or does not have hospital admission privileges. The "qualified professional" will inform the patient that the physician performing the procedure, medical or surgical, does or does not have hospital admission privileges. The "does" or "does not" have hospital admission privileges... will be circled on the "screening sheet". The "qualified professional" will then sign the "screening sheet" stating that the hospital admission privileges and the remainder of regulated information has been provided to patient.

Until, the new Surgery/Medical Appointment Screening Sheet is implemented. The "qualified professional" will document that the patient has been informed of the hospital admission status of the physician performing the procedure on the current "screening sheet."

Diana T. Ramas, PA-C, reviews and speaks with each patient scheduled. Diana, will be in charge of assuring the documentation is correct.

This Plan of Correction has been implemented since June 22, 2015.

Enclosed are the revised Surgery/Medical Appointment Screening Sheet and Making Abortion Appointments Surgical and Medical forms.

Deficiency

E 146 0306 (A) Personnel Records

10A-14E. 0306 (a) Application. Each prospective employee or contractual employee must submit an application for employment which includes education, training, experience and references.

PLAN OF CORRECTION

The employee stated in this deficiency is no longer assigned to "Recovery Charge". She is no longer administering medications oral or injectable. She has been assigned to non- licensed staff positions such as counselling patients, recovery assist and supporting the patient during surgery.

Any person applying for employment with Carolina Center for Women and are a licensed medical professional will need to provide Carolina Center for Women with the actual North Carolina license prior to being hired. This will ensure that the employee will not be assigned to an area in which she is not qualified.

Diana T. Ramas, PA-C will ensure that employees are only assigned to areas that their license allows. Non-licensed staff will be limited to non- medicating duties, and non pre-op or post-op assessment duties.

Diana T. Ramas, PA-C will ensure that all licenses are provided by prospective employees. Once employed, Diana will ensure licenses are updated as required by the specific North Carolina licensing board.

The corrective action will start July 6, 2015 and continuous monitoring by Diana T. Ramas,PA-C

Deficiency

E 151 0307 Nursing Service

Deficiency

E 151 0307 Nursing Service

10A-14E .0307 (a) There shall be a minimum of one registered nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times when Patients are in the facility.

PLAN OF CORRECTION

Amy Nutt has completed the NCLEX-RN on Thursday, June 25, 2015. Amy Nutt is employed by Carolina Center for Women as a part time employee. On July 2, 2015 License Verification/North Carolina Board of Nursing received.

Amy Nutt has post-operative, recovery room experience from previous position with Planned Parenthood of Vermont.

Sandee Champion, RN is employed by Carolina Center for Women as a constant prn RN. Sandee is scheduled every Saturday and wil provides coverage for Amy if needed during the week.

Sandee Champion, RN has post-operative/ recovery room experience. Sandee worked in the recovery room with Planned Parenthood of Charlotte 1998 to 1999. Sandee has worked as "Recovery Charge" with Carolina Center for Women since 1999 to present.

Diana T. Ramas, PA-C will assure that either Amy Nuitt, RN or Sandee Champion, RN will be scheduled on Abortion days. Amy Nutt is a part time employee with Carolina Center for Women and will have to ensure coverage by Sandee Champion, RN if she needs to take time off.

The corrective action will be implemented by July 8, 2015.

Enclosed are copies of Sandee Champion, RN and Amy Nutt, RN current RN license verification.

CAROLINA CENTER FOR WOMEN

Making Abortion Appointments Surgical and Medical

When a person calls requesting an appointment, it must be confirmed that the person on the telephone is the actual patient. Ask "is this appointment for you or are you calling for someone else". If the person on the telephone states it is for someone else, they are informed that the appointment must be made with the actual patient because of the legal information that must be provided to the patient prior to the procedure. If the person on the telephone states she is the actual patient then continue making appointment.

LMP (last menstrual period): Obtain LMP from patient. Patient will be informed that we are estimating gestation from LMP and that an ultrasound will be performed to confirm weeks of pregnancy. If a patient is unsure of LMP and no ultrasound has been performed, patient will be informed that we provide surgical services between 6 to 14 weeks and medical abortion 5 to 8 weeks. The cost for the surgical procedure from 6 to 14 weeks will be provided.
If they want to schedule for the medical abortion they are informed of the cost and informed if they are greater than 8 weeks by ultrasound they will be rescheduled for the surgical procedure.

Weeks: We provide surgical abortions for patient between 6 and 14 weeks. If they are a minor and this is their first pregnancy do not schedule if they are greater than 12 weeks.

Medical abortion services between 5 and 8 weeks gestation.

Age: If patient is a minor then she will need parental consent picture i.d., birth certificate, parent will need picture i.d. If patient does not have picture i.d. she may use a recent yearbook picture. If that not available then she must go to the DMV and obtain a picture i.d.

If parent does not have a birth certificate, they may use a recent tax form which claims patient as a Dependent

The patient may obtain a judicial by pass if they do not want to obtain parental consent. Or if they are unable to obtain i.d. or birth certificate prior to appointment
Judicial By pass: 704-686-0620

Medical Abortion Patients may be scheduled for medical abortion if they are between 5 and 8 weeks gestation by LMP. They must be 18 years or older and live less than 2 hours from the facility.

The Following Information Will be Obtained for Medical and Surgical Abortion

Name: First and Last **Legal** name

Allergies: Medicine and latex,

Surgical Hx: Any surgeries

Medical Conditions: Diabetes, High Blood Pressure, Stroke, Heart problems, Seizures, etc. Every patient must be asked if they have been diagnosed with HIV or TB if yes consult Diana
Consult Diana with histories of strokes, seizures, heart problems, blood diseases, blood clots, etc.

Medications: Patient may take their blood pressure and/or diabetic medications as even directed morning of procedure. **If patient on any antianxiety medications such as, Ativan, valium, Xanax, klonipin etc. they are not to take the morning of procedure.**
No pain medications such as hydrocodone, oxycodone etc. to be taken morning of procedure

If unsure about any medical or surgical history please bring to attention of Clinician or physician prior to completing appointment. If Clinician or physician unavailable, inform patient that the provider will have to be consulted prior to confirming the appointment. If patient unable to be seen here, she will b give names and numbers to other facilities that may be able to accommodate her.

Pregnancy Hx: Number of previous pregnancies: deliveries, ectopic, SAB and EABs.

Ultrasound: Enquire if patient has an ultrasound with current pregnancy, date and gestation.

Cost: Dependent upon gestation. The cost of the surgical procedure are as follows; 6 to 10 weeks $320, 11 to 12 weeks $360, 13 weeks $400, 14 weeks $450.

Medical Abortion cost is $500

Funding is available through the National Abortion Federation. The patient has to speak to MJ or Ashley for qualification. The patient will be transferred to them once the appointment has been completed. If not available patient will be informed that they will call her back .

Additional Cost: If patient has Rh negative blood type then a Rhogam injection is required immediately after the procedure or after taking the Mifeprex if having a medical abortion. The cost is $50 for medical abortion patients and surgical patients that are between 6 and 12 weeks. For surgical patients 13 to 14 weeks the cost is $120

Sedation:
(only for surgical ab) All patient's with a driver are offered valium and ibuprofen prior to the procedure at no additional cost. If a patient feels that additional sedation is needed, Stadol may be offered at an additional $100 charge. Stadol is an injectable narcotic. It does not put the patient to sleep. Stadol causes increased relaxation and pain management.

Payment: Cash, Major Credit Cards: Visa, MasterCard, Discover **No American Express, payroll or personal checks.**

Appointment Info: Please consult calendar for dates and times physicians will be in office. Most weeks it is either Tuesday or /Wednesday most Fridays and Saturdays.

Times are dependent upon which physician working that certain day. Morning clinics, patients may be scheduled between 8am and 9am (in 15 minute increments)

Afternoon appointments are made between 1130 am and 1300.

Dates and times may change dependent on physician schedule. Any changes will be posted on all scheduling calanders ASAP

Patient Instructions: **For Surgical patients** :If appointment between 8 am and 9 am: nothing to eat or drink after midnight the night before appointments.. If appointment between 1130 am and 1300 then nothing to eat or drink after 7am to 8am. If the patient scheduled with Dr. Pearson the .patient **must** have a driver and

the

driver **must** check in with the patient.

Patient needs to wear or bring socks and a sweater.

No children allowed in the office

Plan to be in the facility approximately 3 to 4 hours.

Patient must bring government issued picture I.D.. If minor see above.

For Medical Abortion patients; They may eat something light prior to their appointment. No children allowed in office. They may drive themselves They must bring government issued picture I.D.

Required Information:

The following information has to be provided to patient scheduling for either the medical or surgical abortions.

The patient will be given the following information by "qualified professional" (PA, RN or MD). If the patient scheduling for a medical abortion she will be given the risks for medical abortion, surgical abortion (in case medical abortion fails) and risks of continuing pregnancy. If patient scheduling for the surgical procedure then risks of surgical abortion and continuing pregnancy provided. The patient will be informed if the physician has malpractice insurance. The patient will be informed if the physician does or does not have hospital admission privileges. The "qualified professional" will document date, time and sign that all of the above has been provided to the patient.

If qualified professional not available at the time the appointment is being made, the patient will be informed that the qualified professional will contact her at least 24 hours prior to the appointment. Patient will be informed if "qualified "professional" is unable to contact her at least 24 hours prior to the appointment date and time, the appointment will have to be rescheduled to the date that coincides with the patient receiving information.

Patient has to be given the Woman's Right to Know Act website (www.wrtk.ncdhhs.gov) and then transferred to the recording. While patient on phone press transfer key on phone dial 333 and hang up.

If patient is a minor, both the patient and minor must be on the phone to hear all of the above information. The name of the parent, time, and date must be included on scheduling form.

Date, time and initials making appointment must always be included on scheduling sheet.

CAROLINA CENTER FOR WOMEN

Surgery/Medical Appointment Screening Sheet

Date _____ Int_____

Name _____Age _____DOB _____Prev. pt _____

City _____State_____Contact # _____Pt. ID _____

Drug Allergies _____Current Meds _____

Medical/Surgical Hx _____ TB/HIV _____ Treatment completed _____

LMP _____Weeks_____Blood Type_____

Pregnancy Hx: Deliveries _____ SAB__ _____ EAB _____

Amt. quoted Rhogam, additional sedation, post op meds . Acccept cash, Visa, M/C, Discover no checks or Am Ex_____

Appt. Day/Date _____Time_____npo_____

R/S Appt. Day/Date _____ Time _____Price Change _____

R/S Appt. Day/Date _____ Time _____ Price Change _____

==========

On _____at _____The patient given the following information during an individual consultation by telephone/in person.

If a minor (surgical patients only), the patient's parent _____ given the following information _____ at _____.

_____ Medical risks associated with the medical/surgical procedure- risks of infection, hemorrhage, cervical tear of uterine perforation, danget to subsequent pregnancies, including the ability to continue a pregnancy to full term, and adverse psychological effects associated with abortion.

_____ probable gestional age (estimated by LMP or current ultrasound) at the time of abortion to be performed.

_____ medical risks of continuing the pregnancy to term.

_____ the physician providing services at the time of the appointment has malpractice insurance

_____ the physician providing services on the date of the appointment ~~does/ does not~~ have hospital admission privileges within 30 minutes of our facility that offers OB care

_____ all above information provided by "qualified professional" All questions and concerns addressed at this time.

Signature of qualified professional providing information _____

==========

Patient and parent (if minor scheduling for surgery) given the option to receive the following information in person or by telephone.

_____ Patient given the information in person/telephone Date _____ Time _____

_____ Parent (if patient a minor) given information in person/telephone Date _____ Time _____

_____ Patient transferred to recording. Date _____ Time _____

_____ Parent transferred to recording. Date _____ Time _____

_____ Patient informed that she must view the NC state website, www.wrtk.ncdhhs.gov and print/view the designated information at least 24 hours prior to her appointment. If the patient does not have access to the internet she may come _____ into CCFW for a copy of _____ have it mailed to her. If mailed, it must be mailed 72 hours prior to the appointment. Inform patient if some reasons it is not received at least 24 hours prior to her appointment, the appointment will have to be rescheduled to a time that is 24 hours after the material has been received. Mailed on _____

If information mailed - Patient address _____

==========

I have been given all of the information by telephone or in person as dated above. I understand all of the information provided and all of my questions have been answered and all of my concerns addressed.

Patient Signature _____Date _____Time _____

Parent Signature (if patient a minor) _____Witness _____

License Verification

Name:	Sandra Massey Champion
License #:	128277
Nurse Type:	RN Permanent License
Original Date of Licensure:	09/15/1993
Confirmation #:	HYHUNJB1

LICENSE STATUS

Status:	ACTIVE
Compact Status:	MULTI STATE
Expiration Date:	08/31/2015
Charges/Discipline Against License/Privilege:	NO

Important Notes:

- **Multistate Licensure Privilege: Authority to practice as a licensed nurse in a remote state under the current license provided both states are party to the Nurse Licensure Compact and the privilege is not otherwise restricted.**
- **Single State License: Authority to practice as a licensed nurse only in the state of North Carolina and the privilege is not otherwise restricted.**
- **The NC Board of Nursing certifies that it maintains the information for the license verification function of this website and considers it to be a secure, primary source for license verification.**
- **The database used by this web site was last updated 05/12/2014 08:52:37 AM.**

Print Verification | Select Another Verification | Exit Verification Pages

License Verification

Name:	Amy Elizabeth Nutt
License #:	**279828**
Nurse Type:	**RN Permanent License**
Original Date of Licensure:	**07/02/2015**
Confirmation #:	**USO8D384**

LICENSE STATUS

Status:	**ACTIVE**
Compact Status:	**MULTI STATE**
Expiration Date:	**06/30/2017**
Charges/Discipline Against License/Privilege:	**NO**

Important Notes:

- **Multistate Licensure Privilege: Authority to practice as a licensed nurse in a remote state under the current license provided both states are party to the Nurse Licensure Compact and the privilege is not otherwise restricted.**
- **Single State License: Authority to practice as a licensed nurse only in the state of North Carolina and the privilege is not otherwise restricted.**
- **The NC Board of Nursing certifies that it maintains the information for the license verification function of this website and considers it to be a secure, primary source for license verification.**
- **The database used by this web site was last updated 07/02/2015 11:54:34 AM.**

Print Verification | Select Another Verification | Exit Verification Pages

North Carolina Board of Nursing

This is to certify that **Amy Elizabeth Nutt**

has this day been registered according to the laws relating to nursing in the State of North Carolina and is entitled to practice as and to hold and use the title of

Registered Nurse

In Witness Whereof, we the undersigned have hereunto set our hand and caused the seal of this Board to be affixed this the 2nd of July, 2015

Certificate No. 279828

Margaret Ann M. Harrell

EXECUTIVE DIRECTOR

CHAIR

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 2, 2015

Sharon Cannon, Administrator
Crist Clinic For Women
250 Memorial Drive
Jacksonville, NC 28546

Re: State Licensure Survey

Dear Mrs. Cannon,
Thank you and your staff for the assistance and cooperation extended during the state licensure survey at Crist Clinic For Women in Jacksonville, NC on June 16, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Licensing. As discussed at the exit conference, state licensure deficiencies were identified with respect to 10A NCAC 14E .0310 Emergency Back up Services, 10A NCAC .0311 Surgical Services, 10A NCAC 14E .0313 Post-Operative Care, and 10A NCAC 14E .0314(b) Cleaning of Materials and Equipment.

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form, CMS 2567, with the plan of correction added, must be returned to this office, **SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT.** We are unable to accept e-mailed or faxed reports at this time. A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,
Joyce Spinicchia
Joyce Spinicchia, RN, BSN
NurseConsultant
Acute and Home Care Licensure and Certification Section

Enclosures: State Form - Statement of Deficiencies

Acute and Home Care Licensure and Certification Section
http://www.ncdhhs.gov/dhsr/
Phone: (919) 855-4620 ■ Fax: (919) 715-3073
Mailing Address: 2712 Mail Service Center • Raleigh, North Carolina 27699-2712
Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 156	Continued From page 1 access)".	E 156		
E 158	.0311(B) SURGICAL SERVICES 10A-14E .0311 (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) The facility shall have written procedures, supplies and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C. (3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record. (4) The facility shall establish	E 158	Policy manual in place when inspection occurred did not specifically stated that products of conception were to be documented as determined or undetermined in a patient's individual chart. Policy was revised to include such wording stating that Physician examination of POC or lack thereof is to be documented into patient chart. This policy applies to all of the deficiencies noted under E158. A new policy for monitoring patient's chart for documentation of both POC and time patient went to recovery, length of recovery stay and discharge time was written and implemented on 07/27/15. Monitoring of the initial charts will be done by each biller on duty and a daily log will be kept by each for all therapeutic abortion charts listing the patient name, date of service, POC documented or not and recovery times noted as above policy states. Monthly the biller's logs will be compared to the logs in the Surgical Area for compliance and will be the responsibility of the Clinical Supervisor, Bridget Amancio, LPN and should she be unavailable, will be done by the Practice Manager, Sharon Cannon. Policy is attached to this document. Applies to all deficiencies noted under E158 and E161	07/03/2015 07/27/2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 2 procedures for obtaining, identifying, storing and transporting specimens. (5) The facility shall establish a method for follow-up of patients on whom no vitl are seen. This Rule is not met as evidenced by: Based on policy review, review of medical records and staff interview, the physician failed to document the examination of all products of conception post procedure for 7 of 10 patient records reviewed (#4, #5, #6, #7, #8, #9 and #10). The findings include: Review of the policies revealed no policy for documentation requirements of products of conception in medical records. 1. Closed medical record review of Patient #4 revealed a 19 year old female who had a surgical abortion on 2015. Record review revealed no documentation of examination of products of conception post procedure. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical record. 2. Closed medical record review of Patient #5 revealed a 23 year old female who had a surgical abortion on 2015. Record review revealed no documentation of examination of products of conception post procedure. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 3 record. 3. Closed medical record review of Patient #6 revealed a 41 year-old female who had a surgical abortion on /2015. Record review revealed no documentation of examination of products of conception post procedure. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical record. 4. Closed medical record review of Patient #7 revealed a 25 year-old female who had a surgical abortion on /2015. Record review revealed no documentation of examination of products of conception post procedure. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical record. 5. Closed medical record review of Patient #8 revealed a 37 year-old female who had a surgical /2015. Record review revealed no documentation of examination of products of conception post procedure. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical record. 6. Closed medical record review of Patient #9 revealed a 27 year-old female who had a surgical abortion on 2015. Record review revealed no documentation of examination of products of conception post procedure.	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 4 Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical record. 7. Closed medical record review of Patient #3 revealed a 29 year-old female who had a surgical abortion on /2015. Record review revealed no documentation of examination of products of conception post procedure. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in the medical record.	E 158		
E 161	.0313(A) POST-OPERATIVE CARE 10A-14E .0313 (a) Patients whose pregnancy is terminated on an ambulatory basis should be observed in the abortion clinic for a reasonable number of hours, not less than one, to insure that no immediate post-operative complications are present. Thereafter, such patients may be discharged if their course has been uneventful. This Rule is not met as evidenced by: Based on policy review, review of medical records and staff interview, the facility failed to ensure a minimum of one hour observation after a procedure for 8 of 10 patient records reviewed (#3, #4, #5, #6, #7, #8, #9 and #10). The finding include:	E 161	Addressing E161: A new policy for monitoring patient's chart for documentation of both POC and time patient went to recovery, length of recovery stay and discharge time was written and implemented on 07/27/15. Monitoring of the initial charts will be done by each biller on duty and a daily log will be kept by each for all therapeutic abortion charts listing the patient name, date of service, POC documented or not and recovery times noted as above policy states. Monthly the biller's logs will be compared to the logs in the Surgical Area for compliance and will be the responsibility of the Clinical Supervisor, Bridget Amancio, LPN and should she be unavailable, will be done by the Practice Manager, Sharon Cannon. Policy is attached to this document. Applies to all deficiencies noted under E158 and E161 Please note that the original policy stated the patient was to remain in recovery area for at least one hour, but did not state it needed to be documented in patient chart.	07/27/2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 5 Review of the facility's policies revealed no policy for observing a patient for a minimum of one hour after the procedure. 1. Closed medical record review of Patient #3 revealed a 34 year-old female who had a surgical abortion on /2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record. 2. Closed medical record review of Patient #4 revealed a 19 year-old female who had a surgical abortion on 2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record. 3. Closed medical record review of Patient #5 revealed a 23 year-old female who had a surgical abortion on 2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical	E 161		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 6 record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record. 4. Closed medical record review of Patient #5 revealed a 41 year-old female who had a surgical abortion on /2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record. 5. Closed medical record review of Patient #7 revealed a 25 year-old female who had a surgical abortion on 2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record. 6. Closed medical record review of Patient #8 revealed a 37 year-old female who had a surgical 7/2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their	E 161		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 7 required post operative minimum stay but information is not documented in medical record. 7. Closed medical record review of Patient #9 revealed a 27 year-old female who had a surgical abortion on /2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record. 8. Closed medical record review of Patient #3 revealed a 29 year-old female who had a surgical abortion on /2015. Record review revealed no documented time to recovery area post procedure to discharge time. Interview with Registered Medical Assistant on 06/16/2015 at 1500 revealed she was not aware of all state required documentation in medical record. Interview revealed patients do stay their required post operative minimum stay but information is not documented in medical record.	E 161		
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A 14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment	E 165		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 8 shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on policy review, review of medical records and staff interview, the facility failed to maintain a temperature log on a medication refrigerator. The findings include: Review of policies revealed no policy for monitoring of medication refrigerators. Observation during tour of the facility on 06/16/2016 at 1400 revealed a refrigerator with medications present in the nursing station with no temperature log present. Interview with Registered Medical Assistant revealed she was not aware there was not a log kept. Interview revealed she assumed the refrigerator log was in the nursing office and that it is an expectation for temperatures in the medication refrigerator to be checked daily.	E 165	To address deficiencies in E165: Since there was no current policy in the manual addressing this specifically, a form for logging temperatures on a daily basis was developed and will be kept in the cabinet above each unit containing medicines or medical devices etc. Each unit will be assigned a number and the log will coincide with it. As the log pages fill they will be transferred to a binder and made available for inspection at any given time. A procedural amendment was designed to address this particular deficiency and instructions on full compliance. The monitoring of the daily log sheets will be monitored by the Clinical Supervisor, Bridget Arancio, LPN and will be performed at least weekly. If logging is not being performed as it should be, the Practice Manager has explained it is the responsibility of the MA closest to the refrigerator needing monitoring to complete this daily. It was also explained that should this not be done in compliance with the amendment to 10A-14E .0314 Cleaning of materials and equipment, a written report of this non-compliance will become a permanent part of the personnel file. Full compliance date anticipated to be no later than 08/10/15	08/10/2015

CRIST CLINIC FOR WOMEN

PATHOLOGICAL PROCEDURES

PROCEDURE- PATHOLOGICAL SERVICES

PROCEDURE:

1. *All products of conception (POC) 10 weeks to 12 weeks will be gross examined by a physician with written report of identification or lack thereof in patients chart. All POC identified by physician will be sent to Stericycle Incorporated for disposal.*
2. *All products of conception under 10 weeks and or products of conception not identified will be sent to Solstas/Quest Laboratories for examination and written report. All reports from the lab will be imported into the patient's electronic health record.*

ROUTINE SPECIMENS

1. *Place specimen in appropriate size container.*
2. *The amount of formalin fixative fluid will be 10 times the size of the specimen.*
3. *Only one specimen per container.*
4. *Place label on side of container.*
5. *Label specimen clearly and accurately.*
6. *Complete a pathology slip for each specimen. Operating Room personnel will fill this out in detail.*
7. *Any item (tissue or foreign body) removed from the patient will be sent to the pathologist for verification and written report.*

EFFECTIVE DATE:ORIGINAL DATE: 06/01/2013

REVISION DATE: JULY 1, 2014

FIRST REVISION: JULY 3, 2015

AUTHORIZED BY: TAKEY CRIST MD, FACOG, FACS, MEDICAL DIRECTOR

Authorized signature: _____ ***Date:*** 07/03/2015

ORIGINAL EFFECTIVE DATE: JUNE 1, 2013

REVISION DATE: JULY 1, 2014 SECOND REVISION: JULY 3, 2015

PROCEDURE FOR A DILATION AND EVACUATION

POLICY: PROCEDURE FOR A DILATION AND EVACUATION

PROCEDURE:

There is no doubt that an abortion by dilation and evacuation hurts. One of the moin purposes of counseling is to calm the patient enough so that she will be coaperative with the doctor during the procedure. By knowing exactly what will happen and how it will feel will help the patient have control over the situation.

1. *The procedure will take no more than 3 – 5 minutes.*
2. *The first thing a patient will have done is a pelvic exam.*
    a. *The patient will be taken to the bathroom to empty her bladder so she will be more comfortable during the exam and procedure.*

3. After the pelvic exam is completed, the physician will put a speculum in the opening of the vagina to hold it open for the procedure.

4. The physician will take a gauze swab, dip it in a sterile cleaning solution, and clean out the vagina. It feels cold and wet.

5. *The next step is to place a clamp on each side of the cervix to hold it in place- explain that cervix has very few nerves, and patient may not even feel the clamps.*
6. *The next step is to numb or deaden the cervix. The medicine the physician uses is stronger and works faster than the medicine a dentist uses.*
    a. *There is not much feeling in that area, so the patient feels a sting for 2 – 3 seconds until the medicine gets in the cervix and deadens it. She will feel the sting a few times as the doctor numbs around the cervix.*

(continued)

7. *Next, the cervix is dilated – which means to stretch it open. This is done with instruments called pratts. These instruments are shaped like a pen, and start out with a very small one about the size of a pen point. Each one gets a little larger than the one before it. The physician starts with the smallest one, puts it into the cervix, then takes it out- takes next larger one, puts it in, then takes it out. Assure patient she will not feel this because the cervix has been deadened. Explain that at this time she may feel cramping that feels like cramps on the first day of her period. If she has never experienced period cramps, she will probably only feel sensations, but if she usually has period cramps, she will feel cramping like her period at this time.*

8. *Now the physician is ready for the last step which is to clean out the uterus. He does this with a suction machine. The machine has a long tube that comes from it with a suction catheter on the end of it which he puts up into the uterus. When the machine is turned on, the patient hears a lot of noise, like a motor running.*

9. *When the doctor finishes, one or two tampons will be inserted into the vagina. They are used as a packing to absorb the initial blood loss.*

10. *After the procedure is completed, the patient will get up, put a sanitary pad in her underwear, get dressed, and go to the Recovery Room. She will take her medications, antibiotic and pain meds. Refreshments will be given if desired. She will stay for one hour or longer so her blood pressure can be rechecked and to verify she is not bleeding too heavily before being discharged. Full documentation of time to recovery area and time discharged shall be noted in the patient's chart as well as on the daily procedural log. Under NO circumstances will a patient be discharged prior to one hour in the recovery area.*

11. *Go over After An Abortion sheet.*

12. *Explain methods of birth control available.*

    - *Birth control pills- to take as instructed prior to discharge.*
    - *IUD- put in on six week recheck appointment.*
    - *Depo-Provera 150 mg IM injection given once every 12 weeks for contraception*

APPROVED BY: TAKEY CRIST, MD, FACOG, FACS

ORIGINALLY APPROVED: 06/01/13 REVISION APPROVED: 07/01/2014

REVISION DATE: July 3, 2015

SIGNATURE OF APPROVAL: T MD DATE: 07/03/2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING _____ B. WING _____	06/16/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

RM 98.

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 156	.0310 EMERGENCY BACK-UP SERVICES 10A-14E .0310 The facility shall provide intervention for emergency situations. These provisions shall include but are not limited to: (1) Basic cardio-pulmonary life support; (2) Emergency protocols for: (a) Venous access supplies; (b) Air-way support and oxygen; (c) Bag-valve mask unit with oxygen reservoir, and (d) Suction machine; (3) Emergency lighting available in the operating room; and (4) Ultrasound equipment. This Rule is not met as evidenced by: Based on observation during tours and staff interviews, the facility failed to provide supplies for emergency interventions for emergency situations. The findings include: Observations during tour on 06/16/2015 1430 revealed there were no supplies for venous access (starting IV's), no bag-valve mask unit with oxygen reservoir (BVM) and no suction machine for airway suction available for use in an emergency situation. Tour revealed a portable oxygen cylinder with a nasal cannula available for emergency oxygen needs. Interview with Registered Medical Assistant (RMA) on 06/16/2015 at 1430 during tour revealed if an emergency arises they call 911. Interview revealed RMA stated "Emergency Medical Services responds so fast they can be at the clinic before IV would be started (venous	E 156	Ambu bag was ordered 07/20/15 and delivered to Clinic on 07/22/15. Was put into service on that date. AED unit was ordered on 07/20/15 and arrived at Clinic on 07/23/15 and was put into service on that date. IV solution and supplies for venous access were ordered from McKesson on 07/07/15 and placed into service upon delivery on 07/16/15. An emergency suction machine was ordered on 07/30/15 and will be placed into service no later than 08/10/15 which is the outside of the delivery anticipation date. Monitoring of the AED and suction set will be added to the current list of equipment that has preventative maintenance performed yearly by Modern Biomedical Technologies. Invoices are attached for above equipment with exception of IV supplies. All of these supplies are to be monitored for any deficiencies or problems and Modern Biomedical is to be called to correct the problem. The monitoring will be carried out on a monthly schedule and noted on the daily TA logs that these items were checked. Cross-check for this will be responsibility of Clinical Supervisor, Bridget Amancio, LPN	08/10/2015

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
	PRACTICE MANAGER	07/28/15

ATTACHMENT 2

TEST TESTPATIENT MRN Birthday **1982-01-04** Phone **9101234567**

Visited on: 2015 Jul 20 10:39 (Age at visit: 33 years) Last edited by: Tabitha Feldmeier on 2015-07-20

Medications

Combivent 18 mcg-103 mcg-/inh inhalation aerosol , 1-2 puffs prn symptoms

Allergies

No known allergies

Objective

IUP: ???weeks?? days by ultrasound performed on ??/??/2015
Procedure Performed:
Paracervical Block
Xylocaine1%
Betadine Douche
Quality of Anesthesia
Pitocin
Methergine
Valium
Other drugs Administered:
Volume of Tissue Obtained:
10 cc
20 cc
30 cc
40 cc
50 cc
100 cc
Tissue seen and examined by physician on light table under magnifying lamp: chorionic villi/fetal head/spine/extremities/placenta
Complications:
NONE
Hemorrhage
Cervical Laceration
Perforation of Uterus
Instruments Used:
Sterile Gloves
Plastic Speculum- Small
Plastic Speculum- Medium
Single Tooth Tenaculum ?? size
Sound
Disposable Syringe 20 cc
Disposable Syringe 30 cc
Dilators:
20 gauge 3 inch Spinal Needle
Straight Suction Catheter #?????
Collection Set:
Curet:
Tampon
Other:
Time of Procedure:
Time to Recovery:
Time of Discharge:

ATTACHMENT 3

CRIST CLINIC FOR WOMEN

ORIGINAL EFFECTIVE DATE: JULY 27, 2015

PROCEDURE FOR MONITORING CHARTING COMPLETION ON ABORTION PATIENTS

POLICY: MONITORING PATIENT CHARTS FOR COMPLETION OF REQUIRED ELEMENTS

PROCEDURE:

Each chart will be reviewed by one of the billing staff and logged with identifying information, regarding whether or not products of conception were noted on patient chart, if the specimen was not adequate and sent to pathology for review and if chorionic villi were or were not noted. As this chart review is done an answer of yes or no under heading of POC NOTED is all that is required. The same will be done for recovery area entry time and discharge time documentation on the patient's chart.

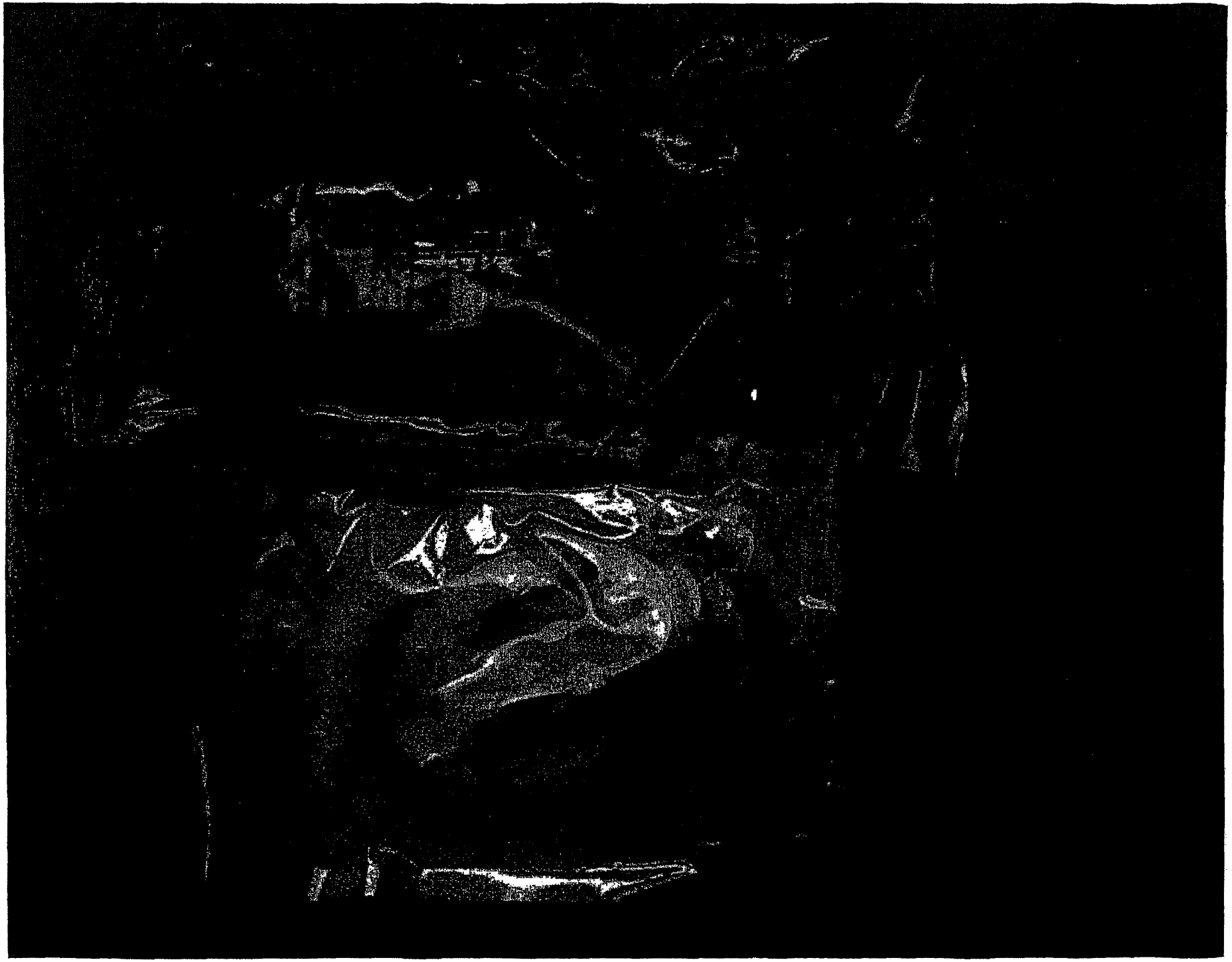
Each biller shall maintain an individual record indicating the above and at the end of each month, the logs will be compared with the logs maintained in the surgical area for comparison. This will be monitored by either the Practice Administrator or Clinical Support Staff Supervisor.

If the logs are found to match with no disparity, they will be attached to the back of the logs from the surgical area for that month. If a disparity is noted, verification of missing information will be located and an addendum to the patient's chart completed and signed off by performing physician.

APPROVED BY TAKEY CRIST, MD, FACOG, FACS

ORIGINALLY APPROVED ON JULY 27, 2015

SIGNATURE OF APPROVAL: MD 07/27/2015



ATTACHMENT 3

	Normal Range 2-8 C / 35-46 F			MONTH-	YEAR	
DATE	TEMP	Time	Initials	Corrective Action Taken	Re -Temp	Time
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Personnel:

Kim Shields- _____

Jean Mitchell- _____

Cynthia Hopkins - _____

Jean Ditmer- _____

Ashley Gilchrist- _____

Heydi Juarez – _____

Bridget Amancio, LPN _____ Clinical Supervisor

ATTACHMENT 4

CRIST CLINIC FOR WOMEN

ORIGINAL EFFECTIVE DATE: 07/08/2015

PROCEDURE: AMMENDMENT TO 10A-14E .0314 CLEANING OF MATERIALS AND EQUIPMENT

POLICY: REFRIGERATOR MONITORING LOGS

PROCEDURE: EACH INDIVIDUAL REFRIGERATOR THAT STORES MEDICAL SUPPLIES INCLUDING BUT NOT LIMITED TO MEDICATIONS ARE TO HAVE THE TEMPERATURES RECORDED ON AN INDIVIDUAL LOG FOR THAT PARTICULAR UNIT. THIS MUST BE DONE AT MINIMUM ONCE PER DAY. THE LOG IS TO BE KEPT ACCESSIBLE FOR INSPECTION NEAR OR AROUND EACH UNIT. THE MONITORING OF COMPLIANCE WITH THIS WILL BE DONE BY THE CLINICAL SUPERVISOR.

REQUIREMENTS ON LOG ARE DATE, TEMPERATURE, TIME CHECKED, INITIALS OF PERSON CHECKING UNIT, CORRECTIVE ACTION IF ANY TAKEN, RE-TEMP IF REQUIRED AFTER CORRECTIVE ACTION AND THE TIME IT WAS TAKEN.

AUTHORIZED BY: TAKEY CRIST, MD, FACOG, FACS, MEDICAL DIRECTOR

APPROVAL SIGNATURE: MD DATE: 07/08/2015

amazonsmile

Final Details for Order #110-4313785-4185831

Print this page for your records.

Order Placed: July 20, 2015
Amazon.com order number: 110-4313785-4185831
Order Total: $25.11
Supporting: Wounded Warrior Project

Shipped on July 20, 2015

Items Ordered	**Price**
1 of: *Adult BVM (Bag Valve Mask)* Sold by: GoodDeal Resources (seller profile) Condition: New	$19.41

Shipping Address: Sharon Cannon 250 MEMORIAL DR JACKSONVILLE, NC 28546-6332 United States	Item(s) Subtotal: $19.41 Shipping & Handling: $5.70 Total before tax: $25.11 Sales Tax: $0.00 **Total for This Shipment: $25.11**
Shipping Speed: Standard Shipping	

Payment information

Payment Method:	Item(s) Subtotal: $19.41 Shipping & Handling: $5.70 Total before tax: $25.11 Estimated tax to be collected: $0.00 **Grand Total: $25.11**
Billing address Sharon Cannon 120 Peartree Lane Richlands, NC 28574 United States	
Credit Card transactions	: July 20, 2015: $25.11

To view the status of your order, return to Order Summary.

Please note: This is not a VAT invoice.

amazonsmile

Final Details for Order #110-8972086-7500224

Print this page for your records.

Order Placed: July 20, 2015
Amazon.com order number: 110-8972086-7500224
Order Total: $1,199.00
Supporting: Wounded Warrior Project

Shipped on July 21, 2015

Items Ordered	**Price**
1 of: *Philips Value Package* Sold by: PurchaseAEDs (seller profile) Condition: New Authorized Philips HeartStart Distributor	$1,199.00

Shipping Address:
Sharon Cannon
250 MEMORIAL DR
JACKSONVILLE, NC 28546-6332
United States

Shipping Speed:
Standard

Item(s) Subtotal:	$1,199.00
Shipping & Handling:	$0.00
Total before tax:	$1,199.00
Sales Tax:	$0.00
Total for This Shipment:	**$1,199.00**

Payment information

Payment Method:

Billing address
Sharon Cannon
120 Peartree Lane
Richlands, NC 28574
United States

Item(s) Subtotal:	$1,199.00
Shipping & Handling:	$0.00
Total before tax:	$1,199.00
Estimated tax to be collected:	$0.00
Grand Total:	**$1,199.00**

Credit Card transactions July 21, 2015: $1,199.00

To view the status of your order, return to Order Summary.

Please note: This is not a VAT invoice.

amazonsmile

Final Details for Order #113-3447497-4409831

Print this page for your records.

Order Placed: July 30, 2015
Amazon.com order number: 113-3447497-4409831
Order Total: $13.33

Shipped on July 31, 2015

Items Ordered	**Price**
1 of: *Full Suction Kit (800cc bottle, 72" blue-tip tubing, and AG5604 filter set)* Sold by: Direct Care Store (seller profile) Condition: New	$18.18

Shipping Address:
Sharon Cannon
250 MEMORIAL DR
JACKSONVILLE, NC 28546-6332
United States

Shipping Speed:
Standard

Item(s) Subtotal:	$18.18
Shipping & Handling:	$0.00
Total before tax:	$18.18
Sales Tax:	$0.00
Rewards Points:	-$4.85
Total for This Shipment:	**$13.33**
Total paid by Rewards Points:	**-$4.85**

Payment information

Payment Method:

Rewards Points

Billing address
Sharon Cannon
120 Peartree Lane
Richlands, NC 28574
United States

Item(s) Subtotal:	$18.18
Shipping & Handling:	$0.00
Total before tax:	$18.18
Estimated tax to be collected:	$0.00
Rewards Points:	-$4.85
Grand Total:	**$13.33**

Credit Card transactions : July 31, 2015: $13.33

To view the status of your order, return to Order Summary.

Please note: This is not a VAT invoice.

CRIST CLINIC FOR WOMEN

ORIGINAL EFFECTIVE DATE: 07/08/2015

PROCEDURE: AMMENDMENT TO 10A-14E .0314 CLEANING OF MATERIALS AND EQUIPMENT

POLICY: REFRIGERATOR MONITORING LOGS

PROCEDURE: EACH INDIVIDUAL REFRIGERATOR THAT STORES MEDICAL SUPPLIES INCLUDING BUT NOT LIMITED TO MEDICATIONS ARE TO HAVE THE TEMPERATURES RECORDED ON AN INDIVIDUAL LOG FOR THAT PARTICULAR UNIT. THIS MUST BE DONE AT MINIMUM ONCE PER DAY. THE LOG IS TO BE KEPT ACCESSIBLE FOR INSPECTION NEAR OR AROUND EACH UNIT. THE MONITORING OF COMPLIANCE WITH THIS WILL BE DONE BY THE CLINICAL SUPERVISOR.

REQUIREMENTS ON LOG ARE DATE, TEMPERATURE, TIME CHECKED, INITIALS OF PERSON CHECKING UNIT, CORRECTIVE ACTION IF ANY TAKEN, RE-TEMP IF REQUIRED AFTER CORRECTIVE ACTION AND THE TIME IT WAS TAKEN.

AUTHORIZED BY: TAKEY CRIST, MD, FACOG, FACS, MEDICAL DIRECTOR

APPROVAL SIGNATURE: ; MD DATE: 07/08/2015

ORIGINAL EFFECTIVE DATE: 07/08/2015

PROCEDURE: AMMENDMENT TO 10A-14E .0314 CLEANING OF MATERIALS AND EQUIPMENT

POLICY: REFRIGERATOR MONITORING LOGS

PROCEDURE: EACH INDIVIDUAL REFRIGERATOR THAT STORES MEDICAL SUPPLIES INCLUDING BUT NOT LIMITED TO MEDICATIONS ARE TO HAVE THE TEMPERATURES RECORDED ON AN INDIVIDUAL LOG FOR THAT PARTICULAR UNIT. THIS MUST BE DONE AT MINIMUM ONCE PER DAY. THE LOG IS TO BE KEPT ACCESSIBLE FOR INSPECTION NEAR OR AROUND EACH UNIT. THE MONITORING OF COMPLIANCE WITH THIS WILL BE DONE BY THE CLINICAL SUPERVISOR.

REQUIREMENTS ON LOG ARE DATE, TEMPERATURE, TIME CHECKED, INITIALS OF PERSON CHECKING UNIT, CORRECTIVE ACTION IF ANY TAKEN, RE-TEMP IF REQUIRED AFTER CORRECTIVE ACTION AND THE TIME IT WAS TAKEN.

AUTHORIZED BY: TAKEY CRIST, MD, FACOG, FACS, MEDICAL DIRECTOR

APPROVAL SIGNATURE: ; MD DATE: 07/08/2015

CRIST CLINIC FOR WOMEN

ORIGINAL EFFECTIVE DATE: JULY 27, 2015

PROCEDURE FOR MONITORING CHARTING COMPLETION ON ABORTION PATIENTS

POLICY: MONITORING PATIENT CHARTS FOR COMPLETION OF REQUIRED ELEMENTS

PROCEDURE:

Each chart will be reviewed by one of the billing staff and logged with identifying information, regarding whether or not products of conception were noted on patient chart, if the specimen was not adequate and sent to pathology for review and if chorionic villi were or were not noted. As this chart review is done an answer of yes or no under heading of POC NOTED is all that is required. The same will be done for recovery area entry time and discharge time documentation on the patient's chart.

Each biller shall maintain an individual record indicating the above and at the end of each month, the logs will be compared with the logs maintained in the surgical area for comparison. This will be monitored by either the Practice Administrator or Clinical Support Staff Supervisor.

If the logs are found to match with no disparity, they will be attached to the back of the logs from the surgical area for that month. If a disparity is noted, verification of missing information will be located and an addendum to the patient's chart completed and signed off by performing physician.

APPROVED BY TAKEY CRIST, MD, FACOG, FACS

ORIGINALLY APPROVED ON JULY 27, 2015

SIGNATURE OF APPROVAL: MD 07/27/2015

CRIST CLINIC FOR WOMEN

ORIGINAL EFFECTIVE DATE: JULY 27, 2015

PROCEDURE FOR MONITORING CHARTING COMPLETION ON ABORTION PATIENTS

POLICY: MONITORING PATIENT CHARTS FOR COMPLETION OF REQUIRED ELEMENTS

PROCEDURE:

Each chart will be reviewed by one of the billing staff and logged with identifying information, regarding whether or not products of conception were noted on patient chart, if the specimen was not adequate and sent to pathology for review and if chorionic villi were or were not noted. As this chart review is done an answer of yes or no under heading of POC NOTED is all that is required. The same will be done for recovery area entry time and discharge time documentation on the patient's chart.

Each biller shall maintain an individual record indicating the above and at the end of each month, the logs will be compared with the logs maintained in the surgical area for comparison. This will be monitored by either the Practice Administrator or Clinical Support Staff Supervisor.

If the logs are found to match with no disparity, they will be attached to the back of the logs from the surgical area for that month. If a disparity is noted, verification of missing information will be located and an addendum to the patient's chart completed and signed off by performing physician.

APPROVED BY TAKEY CRIST, MD, FACOG, FACS

ORIGINALLY APPROVED ON JULY 27, 2015

SIGNATURE OF APPROVAL: MD 07/27/2015

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

April 29, 2014

Dr. Takey Crist, CEO
Crist Clinic For Women
250 Memorial Drive
Jacksonville, NC 28546

Re: Recertification Survey

Dear Dr. Crist,

Thank you and your staff for the assistance and cooperation extended during the Recertification survey at Crist Clinic For Women in Jacksonville, NC from March 5, 2014 through March 6, 2014. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Licensure for Abortion Clinics. As a result of the survey, standard level deficiencies were identified

Enclosed please find STATE Form , "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies should be submitted and include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed for STATE form, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

/Cecilia Boone/

Cecilia Boone, RN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Enclosures: STATE form Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

5/20/14 CBS

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered. This Rule is not met as evidenced by: Based on closed medical record reviews and staff interviews the facility failed to maintain 2 of 15 medical records inclusive of a witnessed, voluntarily-signed consent for each surgery or procedure with the signature of the physician performing the procedure. (#14 and #9). The Findings include: 1. Medical record review of patient #14 revealed the patient was 6 weeks 5 days pregnant. Record review revealed the patient had a surgical abortion procedure (SAB) completed on /2014. Review of the record revealed a witnessed voluntary signed consent for the SAB signed by the patient. Review of the consent revealed no documentation of the signature of the	E 137	CORRECTIVE ACTION DEFICIENCY E137 – AS OF 3/13/2014 ALL PATIENT CONSENT FORMS HAVE BEEN SIGNED WITNESSED AND SIGNED BY PHYSICIAN PERFORMING PROCEDURE, will be monitored by Director of Nurses, Frances Thompson R.N.	3/13/14

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 1 physician performing the SAB. 2. Medical record review of patient #9 revealed the patient was 11 weeks pregnant. Record review revealed the patient had a surgical abortion procedure (SAB) completed on /2014. Review of the record revealed a witnessed voluntary signed consent for the SAB signed by the patient. Review of the consent revealed no documentation of the signature of the physician performing the SAB. Interview with RN #1 on 03/06/2014 at approximately 1500 revealed there was no documentation available of the physician performing the SAB had signed the consent for patients #14 and #9.	E 137		
E 141	.0305(E) MEDICAL RECORDS 10A-14E .0305 (e) The facility shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least patient name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, and date and time of procedure. This Rule is not met as evidenced by: Based on procedure log review and staff interview the facility failed to maintain a daily procedure log inclusive of the time of the procedure. The Findings include: Review of the facility's daily procedure log revealed no documentation of the time of the procedure.	E 141	CORRECTIVE ACTION DEFICIENCY E 141 - 10A-14E.305 AS OF 3/13/14 THE DAILY PROCEDURE LOG OF ALL ABORTION PATIENTS CONTAINS PROCEDURE DATE, TIME OF ADMISSION, GESTATIONAL AGE, TIME OF PROCEDURE, TIME OF DISCHARGE AND NAME OF ATTENDING NURSE AND PHYSICIAN PERFORMING THE PROCEDURE.	3/13/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 141	Continued From page 2 Interview with the facility Registered Nurse (RN) on 03/06/2014 at 0930 revealed the facility had in the past documented the time of the procedure on the daily procedure log. The interview revealed it was not done any more. The interview revealed the RN was not sure how long the procedure time had not been documented on the daily procedure log. The interview indicated the RN was not aware of the requirement for the time of the procedure to be documented on the daily procedure log.	E 141		
E 147	.0306(B) PERSONNEL RECORDS 10A-14E .0306 (b) Job Descriptions: (1) The facility shall have a written description which describes the duties of every position. (2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required. (3) The facility shall review annually and update all job descriptions, and shall provide a current copy to each employee or contractual employee assigned to the position. This Rule is not met as evidenced by: Based on personnel file review, job description review and staff interview the facility failed to annually review the job description in 1 of 1 RN positions reviewed (RN#1). The Findings include:	E 147	CORRECTIVE ACTION DEFICIENCY E147.0306 AN UPDATED JOB DESCRIPTION HAS BEEN WRITTEN WITH ALL DUTIES, QUALIFICATIONS, EDUCATION, TRAINING EXPERIENCE LICENSE OR CERTIFICATION AND SIGNED BY DR CRIST AS WELL AS EMPLOYEE; TO BE REVIEWED ANNUALLY	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0030	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CRIST CLINIC FOR WOMEN	250 MEMORIAL DRIVE JACKSONVILLE, NC 28546

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 147	Continued From page 3 Review of RN #1's personnel file revealed a signed job description for the RN position. Review of the job description revealed no date of review. Further review of the job description revealed 1997 documented last review of the job description. Personnel file review did not reveal any documentation of the annual review of the job description. Interview on 03/06/2014 at 1030 with RN #1 revealed there had been no update or review of her job description. The interview revealed the documentation indicated there had not been reviewed since 1997.	E 147		

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

April 13, 2015

Kenya Mauldin, Director
Family Reproductive Health, In
700 Hebron Street
Charlotte, NC 28273

Re: State Re-Certification Survey

Dear Ms. Mauldin,

Thank you and your staff for the assistance and cooperation extended during the state Re-Certification survey at Family Reproductive Health, In in Charlotte, NC on March 25, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Governing the Certification of Clinics for Abortions. As discussed at the exit conference, a deficiency was identified with respect to .0311 Identification specifics of Products of Conception .

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiency. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form State Form, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN
NurseConsultant, Lead
Acute and Home Care Licensure and Certification Section

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0026	A. BUILDING: _____ B. WING _____	03/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FAMILY REPRODUCTIVE HEALTH, IN	700 HEBRON STREET CHARLOTTE, NC 28273

Request Addendum into 4/28/2015

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	.0311(B) SURGICAL SERVICES 10A-14E .0311 (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) The facility shall have written procedures, supplies and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C. (3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record. (4) The facility shall establish procedures for obtaining, identifying, storing and transporting specimens. (5) The facility shall establish a method for follow-up of patients on	E 158	• 0311(B) SURGICAL SERVICES The physician performing the abortion always examines & documents the uterine contents/ products of conception (P.O.C.) for presence or absence of chorionic villi or fetal parts or the amniotic sac, prior to patient discharge, "Normal products of conception for gestational age _YES_NO". "Products of conception appeared _normal _abnormal. *The physician will now document the findings in longhand specifically the presence or absence of chorionic villi or fetal parts or the amniotic sac to reflect exact language required by 10A NCAC 14E.0311. **We will revise the surgery notes, ("Procedure") form to reflect the exact language required by 10A NCAC 14E.0311.	* 4.24.15 ** 5.20.15

Division of Health Service Regulation
LABORATORY DIRECTO 'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE: RN

(X6) DATE: 4.22.15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0026	A. BUILDING: _____ B. WING _____	03/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FAMILY REPRODUCTIVE HEALTH, IN	700 HEBRON STREET CHARLOTTE, NC 28273

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 1 whom no villi are seen. This Rule is not met as evidenced by: Based on policy review, medical record reviews and staff interview the physician performing the surgical abortion procedure failed to document in the patient's medical record specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac in the products of conception (POC) in 8 of 8 patients having a surgical abortion procedure (#'s 1, 2, 5, 6, 7, 8, 9,and 10). The Findings include: Review of clinic policy "PROTOCOL FOR 'NO CHORIONIC VILLI'", revealed "It is the policy of XX(name of clinic) to send uterine contents specimens to Physicians Lab Service for pathological-microscopic examination upon order by physician. All specimens will be examined immediately post-op for presence of chorionic villi and results will be documented in patients chart 1. Medical record review of Patient #1 revealed the patient had a surgical abortion procedure on /2015. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. 2. Medical record review of Patient #2 revealed the patient had a surgical abortion procedure on /2015. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. 3. Medical record review of Patient #5 revealed the patient had a surgical abortion procedure on /2015. Record review did not reveal documentation of chorionic villi and fetal parts or	E 158		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0026	A. BUILDING: _____ B. WING _____	03/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FAMILY REPRODUCTIVE HEALTH, IN	700 HEBRON STREET CHARLOTTE, NC 28273

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 158	Continued From page 2 amniotic sac in the POC. 4. Medical record review of Patient #6 revealed the patient had a surgical abortion procedure on /2014. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. 5. Medical record review of Patient #7 revealed the patient had a surgical abortion procedure on /2015. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. 6. Medical record review of Patient #8 revealed the patient had a surgical abortion procedure on /2015. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. 7. Medical record review of Patient #9 revealed the patient had a surgical abortion procedure on /2014. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. 8. Medical record review of Patient #10 revealed the patient had a surgical abortion procedure on /2014. Record review did not reveal documentation of chorionic villi and fetal parts or amniotic sac in the POC. Interview with administrative staff #1 and #2 via phone on /2015 at 1400 revealed there was no further documentation available of the physician's identification of specifics of the POC.	E 158	We appreciate this report from the Department. Our intention is to stay in compliance with all regulations pertaining to our practice. Feedback from the Department is essential in letting us know when our forms + policies need clarification or correction. Thank you for your recent detailed inspection. We welcome the Department's input.	

Family Reproductive Health

MAY 05 2015

CBB 05/08/15

Addendum to Plan of Correction for survey completed on 3.25.15

. 0311 (B) Surgical Services

E158 The physician performing the abortion always examines + documents the uterine contents / products of conception (P.O.C) for presence or absence of chorionic villi AND fetal parts or the amniotic sac, prior to pt discharge, "Normal products of conception for gestational age _YES _No". Products of conception appeared _normal _abnormal.

* The physician will now document the findings in longhand specifically the presence or absence of chorionic villi AND fetal parts or the amniotic sac to reflect exact language required by 10A NCAC 14E. 0311. 4.29.15

, RN 4.29.15

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

October 16, 2014

Tammy Chalmers, Administrator
Hallmark Women's Clinic
1919 Gillespie Street
Fayetteville, NC 28306

Re: Complaint Investigation(s): NC00093287

Dear Ms. Chalmers:

Thank you and your staff for the assistance and cooperation extended during the complaint investigation and recertification survey at Hallmark Women's Clinic in Fayetteville, NC from October 8, 2014 through October 9, 2014. The investigation was conducted in order to determine the facility's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortions as well as to determine the validity of the complaint(s).

As discussed in the exit conference, 0 of 1 allegations were substantiated. Furthermore, as a result of the investigation, deficiencies were identified with respect to 10A NCAC 14E.0314 Cleaning of Materials and Equipment.

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed State Plan, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 218-9458.

Sincerely,

Lynn Ethridge, RN, BSN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Enclosures: CMS 2567 Statement of Deficiencies

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	10/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

✓ CBS 02/05/2015

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on review of facility policy, autoclave testing log review, observation during tour and staff interview, the facility failed to control the risk of infection by failing to perform biological testing on the autoclave to ensure surgical instruments were sterile. The findings include: Review of the facility policy, "Attestation of Autoclave", not dated, revealed, "POLICY: In order to assure adequate sterilization of essential surgical equipment by the autoclave, testing with 3M Attestation Indicators and incubator is required. Testing of the primary autoclave will be performed once each week and results of the test recorded in the quality control book (provided by the manufacturer of the testing kit) by the surgical technician and supervised by the clinic manager...". Observation during tour of the facility on 10/09/2014 revealed 2 autoclaves in the equipment processing room located between the two procedure rooms. Review of the autoclave testing log revealed the last documented Attest	E 165		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE
02/05/2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	10/09/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 1 performed once each week and results of the test recorded in the quality control book (provided by the manufacturer of the testing kit) by the surgical technician and supervised by the clinic manager...". Observation during tour of the facility on 10/09/2014 revealed 2 autoclaves in the equipment processing room located between the two procedure rooms. Review of the autoclave testing log revealed the last documented Attest (biological testing) was done on 03/22/2014 (6 months, 17 days ago). Observation of the Attest spore vials revealed the vials expired in November 2006 (7 years, 11 months ago). Interview on 10/09/2014 at 1000 with the surgical technician revealed the testing had not been done since 03/22/2014 because "we haven't done a lot of procedures". Interview revealed the autoclave is used weekly to sterilize surgical equipment. Interview on 10/09/2014 at 1015 with the facility administrator confirmed the autoclave had not been tested weekly per the facility's policy. NC00093287	E 165		

Incubator Monitoring Inspection- Control Testing

Date	Time in incubator	Date	Time Removed	Color Results	Initails
10/13/2014	10:40	10/15/2014	10:40	yellow	MJ
10/20/2014	10:40	10/22/2014	10:40	yellow	MJ
10/27/2014	10:40	10/28/2014	10:40	yellow	MJ
11/3/2014	10:40	11/5/2014	10:40	yellow	MJ
11/10/2014	10:30	11/12/2014	10:50	yellow	MJ
11/17/2014	10 30	11/19/2014	10:40	yellow	MJ
11/24/2014	10:40	11/26/2014	10 50	yellow	MJ
12/1/2014	10:30	12/3/2014	10 50	yellow	MJ
12/8/2014	10 30	12/10/2014	10 50	yellow	MJ
12/15/2014	10 40	12/17/2014	10 50	yellow	MJ
12/22/2014	10 30	12/24/2014	10 40	yellow	MJ
12/29/2014	10 30	12/31/2014	10 40	yellow	MJ
1/5/2015	10 00	1/7/2015	10 30	yellow	MJ
1/12/2015	10 00	1/14/2015	10 30	yellow	MJ
1/19/2015	10 00	1/21/2015	10 30	yellow	MJ
1/26/2014	10 00	1/28/2015	10 30	yellow	MJ
2/2/2015	10 00	2/4/2015	10 30	yellow	MJ
2/9/2015	10 00	2/11/2015	10 30	yellow	MJ
2/16/2015	10 00	2/18/2015	10 30	yellow	MJ

Frank Lapperuta

Autoclave Weekly Cleaning Log

(To be completed once each week on both autoclaves)

Date Cleaned	Autoclave	Time of Day Cleaning Completed	Initals
12/15/2014	Tuttnauer 2340M	9 am	MJ
12/15/2014	Ritter M9	9 15	MJ
12/22/2014	Tuttnauer 2340M	9 am	MJ
12/22/2014	RitterM9	9 15 am	MJ
12/29/2014	Tuttnauer 2340M	9 am	MJ
12/29/2014	Ritter M9	9 15 am	MJ
01/05/2015	Tuttnauer 2340M	9 00 am	MJ
01/05/2015	Ritter M9	9 30 am	MJ
01/12/2015	Tuttnauer 2340M	9 30 am	MJ
01/12/2015	Ritter M9	9 00 Am	MJ
01/19/2015	Tuttnauer 2340M	9 AM	MJ
01/19/2015	Ritter M9	9 30 am	MJ
01/26/2015	Tuttnauer 2340M	9 30 Am	MJ
01/26/2015	Ritter M9	9 am	MJ
02/02/2015	Tuttnauer 2340M	9 am	MJ
02/02/2015	Ritter M9	9 30	MJ
02/09/2015	Tuttnauer 2340M	9 am	MJ
02/09/2015	Ritter M9	9 30	MJ

Autoclave Weekly Cleaning Log

(To be completed once each week on both autoclaves)

Date Cleaned	Autoclave	Time of Day Cleaning Completed	Initals
10/13/2014	Tuttnauer 2340M	9:30	MJ
10/13/2014	Ritter M9	9:30 am	MJ
10/20/2014	Tuttnauer 2340M	9:30	MJ
10/20/2014	RitterM9	9:30 am	MJ
10/27/2014	Tuttnauer 2340M	9:30	MJ
10/27/2014	Ritter M9	9:30 am	MJ
11/3/2014	Tuttnauer 2340M	9:30	MJ
11/3/2014	Ritter M9	9AM	MJ
11/10/2014	Tuttnauer 2340M	9 Am	MJ
11/10/2014	Ritter M9	9 30 AM	MJ
11/17/2014	Tuttnauer 2340M	9 AM	MJ
11/17/2014	Ritter M9	10 30	MJ
11/24/2014	Tuttnauer 2340M	9 AM	MJ
11/24/2014	Ritter M9	10 30	MJ
12/1/2014	Tuttnauer 2340M	9 AM	MJ
12/1/2014	Ritter M9	10 00	MJ
12/8/2014	Tuttnauer 2340M	9 AM	MJ
12/8/2014	Ritter M9	10 00	MJ

Fenal Coppage

Ex 9. 2016

Attest Biological Monitoring Inspection

Date	Sterilizer	Time Placed in Autoclave	Time Placed in Incubator	Date	BI Color	Initials
12/01/2014	Tuttnauer 2340M	9am	930	12/03/2014	Purple	MJ
12/08/2014	Ritter M9	9am	930	12/10/2014	purple	MJ
12/15/2014	Tuttnauer 2340M	930	10:00	12/17/2014	purple	MJ
12/22/2014	Ritter M9	930	10:00	12/24/2014	purple	MJ
12/29/2014	Tuttnauer 2340M	9am	930	12/31/2014	purple	MJ
01/05/2015	Ritter M9	9am	930	01/07/2015	purple	MJ
01/12/2015	Tuttnauer 2340M	9am	930	01/14/2015	purple	MJ
01/19/2015	Ritter M9	9am	930	01/21/2015	purple	MJ
01/26/2015	Tuttnauer 2340M	9am	930	01/28/2015	purple	MJ
02/02/2015	Ritter M9	9am	930	02/04/2015	purple	MJ
02/09/2015	Tuttnauer 2340M	9am	930	02/11/2015	purple	MJ
02/16/2015	Ritter M9	9am	930	02/18/2015	purple	MJ
02/23/2015	Tuttnauer 2340M	9am	930	02/25/2015	purple	MJ
03/02/2015	Ritter M9	9am	930	03/04/2015	purple	MJ

EX 9 - 2014

Attest Biological Monitoring Inspection

Date	Sterilizer	Time Placed In Autoclave	Time Placed In Incubator	Date	BI Color	Initials
10/13/2014	Tuttnauer 2340M	10 am	10:40	10/15/2014	purple	MJ
10/13/2014	Ritter M9	10 am	10:40	10/15/2014	purple	MJ
10/20/2014	Tuttnauer 2340M	10 am	10:40	10/22/2014	purple	MJ
10/20/2014	Ritter M9	10 am	10:40	10/22/2014	purple	MJ
10/27/2014	Tuttnauer 2340M	10 am	10:40	10/29/2014	purple	MJ
10/27/2014	Ritter M9	10 am	10:40	10/29/2014	purple	MJ
11/3/2014	Tuttnauer 2340M	10 am	10:40	11/5/2014	purple	MJ
11/3/2014	Ritter M9	10 am	10:40	11/5/2014	Purple	MJ
11/10/2014	Tuttnauer 2340M	1030	10.50	11/12/2014	purple	MJ
11/10/2014	Ritter M9	10 30	10 50	11/12/2014	purple	MJ
11/17/2014	Tuttnauer 2340M	10:30	10:50	11/19/2014	Purple	MJ
11/17/2014	Ritter M9	1000	10:40	11/19/2014	purple	MJ
11/24/2014	Tuttnauer 2340M	1030	10.40	11/26/2014	purple	MJ
11/24/2014	Ritter M9	10:00	10:40	11/26/2014	purple	MJ

Fem Approved

Autoclave Cleaning Protocol

WARNING: The cleaning solution contains alkaline ingredients. Avoid contact with skin, clothing and eyes. In the event of contact, flush with water. If irritation continues, see M.D. DO NOT ingest.

Equipment Needed: Gloves, protective goggles, apron, cleaning solution and distilled water.

Autoclaves must be cleaned weekly

1.) Drain and refill the reservoir with clean distilled water.
2.) Add one ounce of Speed Clean to the inside of a cool chamber.
3.) Run one unwrapped cycle (shortest cycle) at 270 degrees for 6 minutes.
4.) Instruments should not be sterilized while cleaning the autoclave.
5.) Drain the reservoir and allow the autoclave to cool.
6.) Remove the trays, tray rack and tray plate. Hand wash with water and Speed Clean using a soft cloth. Also wash the strainer mounted on the exhaust hole at the bottom of the chamber. Wipe out the inside of the chamber also using Speed Clean and a soft cloth. Be careful to NOT touch the heating element located inside on the back panel, towards the bottom. DO NOT use steel wool or brushes, they will damage the autoclave.
7.) Re-install components in the chamber. Make sure the tray is pushed to the back of the chamber.
8.) Run a full cycle with no solution, distilled water only.
9.) Drain water and refill with distilled water.

Autoclave is now ready for use

Autoclave Testing Protocol

Autoclaves must be tested weekly

1.) Grab a new Biological Indicator (BI) and write the following info on the sterilizing strip located on the indicator:
    -Machine being cleaned (brand)
    -Load #
    -Date
2.) Place (BI) inside of autoclave with first cleaning cycle.
3.) After BI has remained in autoclave for ONLY one cycle, remove BI and allow to cool before the vial is snapped/crushed
4.) Place vial in incubator and allow it to sit for at least 48 hours.
5.) After 48 hours, remove BI from incubator and log color on Autoclave Testing Log Spreadsheet. When running correctly, BI should turn purple/brown. If BI turns any other color except for purple/brown, bring results to the attention of Management.
6.) Discard BI appropriately
7.) Repeat weekly

Autoclave is now ready for use

Incubator Testing Protocol

Incubator control must be tested weekly

1.) Grab an unused Biological Indicator(BI) and snap/crush it. This breaks the glass ampule that is inside the plastic vial of the BI. *DO NOT run BI through autoclave for incubator testing protocol.*

2.) Place crushed vial inside incubator and let sit for at least 48 hours before reading results.

3.) After 48 hours read results. Results should be yellow. If BI turns any other color except for yellow, bring results to the attention of Management.

4.) Discard BI appropriately.

5.) Repeat weekly to insure incubator is working properly.

10/28/14

In Service

Attest - Steam Sterilization 3 M-

New System Warmed Up - Checked for System Function - OK.

Will plan on System Check on Tuesday - with 48 hr wait period and Spore Test on Thursday weekly.

Tube to be Read & Results Recorded into Log -

Medical Director

Manager

Mary Johnson, RN

AH Form Approved
3/10/2015

State Form: Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
AB0007	A. Building B. Wing	2/5/2015

Name of Facility	Street Address, City, State, Zip Code
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix E0165 Reg. # .0314 LSC	Correction Completed 02/05/2015	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By State Agency	Reviewed By	Date:	Signature of Surveyor:	Date: 03/19/15
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:		Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO
10/9/2014		

Received 4/28/15

4/28/15 VCOB

PRINTED: 03/10/2015
FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered. This Rule is not met as evidenced by: Based on closed medical record reviews and staff interviews the physician performing the procedure failed to sign the voluntary, witnessed signed consent for each surgical abortion procedure in 5 of 11 patients having a surgical abortion procedure (SAB) (#10, #9, #8, #6 and #17). The Findings include: 1. Medical record review of patient # 10 revealed the patient had a SAB on /2015. Record review revealed no documentation of a voluntary witnessed consent for the SAB signed by the physician. Review of the voluntary witnessed consent form in the medical record revealed the section for the physician's signature was blank. Interview with administrative staff on 02/15/2015	E 137	In Service Meeting With All Physicians. Reviewed by Management All Formed Reviewed That Required Physicians - All Records will be Reviewed Daily and Checked For Completion: Completed 2/20/15 In Service Meeting - Record Pulled. Physician Signed - SAB #10	2/20/15

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Medical Director — (X6) DATE: 4/22/15

STATE FORM 6899 — 4LB811 — If continuation sheet 1 of 10

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 1 at 1455 revealed the facility policy was for the physician performing the SAB, to sign the voluntary witnessed consent for the SAB. The interview revealed there was no documentation available of a voluntary witnessed consent signed by the physician for medical record #10. 2. Medical record review of patient # 9 revealed the patient had a SAB on /2015. Record review revealed no documentation of a voluntary witnessed consent for the SAB signed by the physician. Review of the voluntary witnessed consent form in the medical record revealed the section for the physician's signature was blank. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for the physician performing the SAB, to sign the voluntary witnessed consent for the SAB. The interview revealed there was no documentation available of a voluntary witnessed consent signed by the physician for medical record # 9. 3. Medical record review of patient # 8 revealed the patient had a SAB on /2015. Record review revealed no documentation of a voluntary witnessed consent for the SAB signed by the physician. Review of the voluntary witnessed consent form in the medical record revealed the section for the physician's signature was blank. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for the physician performing the SAB, to sign the voluntary witnessed consent for the SAB. The interview revealed there was no documentation available of a voluntary witnessed consent signed by the physician for medical record # 8. 4. Medical record review of patient # 6 revealed	E 137	Completed 2/20/15 #9 at IN Service. Record Pulled and SAB Signed by Physician. #8 Completed 2/20/15 Record Pulled SAB Signed by Physician. Records Reviewed Daily.	2/20/15 2/20/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 2 the patient had a SAB on /2015. Record review revealed no documentation of a voluntary witnessed consent for the SAB signed by the physician. Review of the voluntary witnessed consent form in the medical record revealed the section for the physician's signature was blank. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for the physician performing the SAB, to sign the voluntary witnessed consent for the SAB. The interview revealed there was no documentation available of a voluntary witnessed consent signed by the physician for medical record # 6. 5. Medical record review of patient # 17 revealed the patient had a SAB on /2014. Record review revealed no documentation of a voluntary witnessed consent for the SAB signed by the physician. Review of the voluntary witnessed consent form in the medical record revealed the section for the physician's signature was blank. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for the physician performing the SAB, to sign the voluntary witnessed consent for the SAB. The interview revealed there was no documentation available of a voluntary witnessed consent signed by the physician for medical record #17.	E 137	#6 Record pulled SAB Signed by Physician. Completed 2/20/15 - Recorded Reviewed Daily #17 - Record pulled SAB Signed by Physician Completed 2/20/15 Recorded Reviewed Daily	2/20/15 2/20/15
E 156	.0310 EMERGENCY BACK-UP SERVICES 10A-14E .0310 The facility shall provide intervention for emergency situations. These provisions shall include but are not limited to: (1) Basic cardio-pulmonary life support; (2) Emergency protocols for: (a) Venous access supplies,	E 156	In Service with Management and Medical Staff.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 156	Continued From page 3 (b) Air-way support and oxygen, (c) Bag-valve mask unit with oxygen reservoir, and (d) Suction machine; (3) Emergency lighting available in the operating room; and (4) Ultrasound equipment. This Rule is not met as evidenced by: Based on observations during tour and staff interview the facility staff failed to ensure emergency medications and supplies in the emergency bag and Intravenous (IV) supply box were not expired and available for patient care. The findings include: Observations during tour of the facility on 02/05/2015 at 1044 revealed an emergency bag stored in the recovery area. Observation revealed the following medications were expired: (2) Adenosine 12 mg (milligrams)/4 ml (milliliter) vials expired 05/2013; (1) Epinephrine 1:1000 vial expired 09/2013; (1) Tube Insta Glucose expired 12/2013; (2) Ondansetron 4 mg/2 ml vials expired 11/2013; (1) Pitressin 20 units vial expired 04/2014; (2) Naloxone 0.4 mg ampules expired 08/2014; and (2) Amiodarone HCL 150 mg ampules expired 08/2014. Observation of the emergency IV supply box revealed (1) IV Start Kit expired 04/2010. Interview during tour with a staff registered nurse revealed "we check the emergency box every other month." Interview revealed the staff are suppose to check expiration dates. Interview revealed the medications and IV supplies were available for emergency use. Interview on 02/05/2015 at 1445 with Administrative Management Staff #1 revealed the	E 156	ALL Equptment. Ultrasound Suction machine ER Lighting ALL Equpthment Check and Certified ALL Necessary ER Meds WERE Replaced. (1) AMINOPHYLL (2) EPINEPHRINE (3) NALBUPHINE (4) ADENOSINE (5) EPINEPHRINE (1) VERAPAMIL (2) ONDANSETRON (3) LIDOCAINE BANYAN / ENVIRONMENTAL Recovery Envelope For Returning Expired Medications IV START KIT — Replaced.	3/30/15 2/5/15 2/5/15 2/5/15 2/5/15 2/5/15 2/10/15 2/10/15 2/10/15

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 156	Continued From page 4 facility did not have a policy for expired medications and supplies. Interview confirmed the medications and IV kit were expired.	E 156	Plan placed in Policy and Procedure Book For Disposal of Medication & IV Kits with Hazardous Waste and Needle Collection Dates To Be Listed and Checked Monthly Completed 4/30/15	4/30/15
E 161	.0313(A) POST-OPERATIVE CARE 10A-14E .0313 (a) Patients whose pregnancy is terminated on an ambulatory basis should be observed in the abortion clinic for a reasonable number of hours, not less than one, to insure that no immediate post-operative complications are present. Thereafter, such patients may be discharged if their course has been uneventful. This Rule is not met as evidenced by: Based on closed medical record reviews and staff interviews the staff failed to document observation of the patient for a minimum of one hour after each surgical abortion procedure performed in 4 of 11 patients having a surgical abortion procedure (SAB) (#7, #4, #2 and #3). The Findings include: 1. Medical record review revealed patient # 7 had a SAB performed on /2015. Medical record revealed no documentation by staff the patient was observed for a minimum of one hour (1 hour) post procedure before discharge from the clinic. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for staff to	E 161 E161	In Service Meeting with Management Medical Direction and Nursing Staff Reviewed Discharge Policy and Forms including AMA Against Medical advice Corrected 2/20/15 #7 - Reviewed with Nurse on Duty AMA must be signed If Patient is to	2/20/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 5 observe patients for a minimum of one hour (1 hour) prior to discharge or for patients to sign the voluntary Against Medical Advice (AMA) form if the patient refuses to stay one hour (1 hour) post procedure. The interview revealed there was no documentation available of a voluntary AMA form signed by the patient for medical record # 7. 2. Medical record review revealed patient # 4 had a SAB performed on /2014. Medical record revealed no documentation by staff the patient was observed for a minimum of one hour (1 hour) post procedure before discharge from the clinic. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for staff to observe patients for a minimum of one hour (1 hour) prior to discharge or for patients to sign the voluntary Against Medical Advice (AMA) form if the patient refuses to stay one hour (1 hour) post procedure. The interview revealed there was no documentation available of a voluntary AMA form signed by the patient for medical record # 4. 3. Medical record review revealed patient # 2 had a SAB performed on 2014. Medical record revealed no documentation by staff the patient was observed for a minimum of one hour (1 hour) post procedure before discharge from the clinic. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for staff to observe patients for a minimum of one hour (1 hour) prior to discharge or for patients to sign the voluntary Against Medical Advice (AMA) form if the patient refuses to stay one hour (1 hour) post procedure. The interview revealed there was no documentation available of a voluntary AMA form signed by the patient for medical record # 2.	E 161	Leave prior to the Reviewed 2/20/14 #4 Reviewed with Nurse on Duty 1/14 AMA Form must be Signed by Patient prior To Discharge Reviewed 2/20/14 #2 Reviewed with Nurse on Duty 1/14 AMA Form, must be Signed prior To Discharge From Clinic. 2/20/15	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 6 4. Medical record review revealed patient # 3 had a SAB performed on 19/2014. Medical record revealed no documentation by staff the patient was observed for a minimum of one hour (1 hour) post procedure before discharge from the clinic. Interview with administrative staff on 02/15/2015 at 1455 revealed the facility policy was for staff to observe patients for a minimum of one hour (1 hour) prior to discharge or for patients to sign the voluntary Against Medical Advice (AMA) form if the patient refuses to stay one hour (1 hour) post procedure. The interview revealed there was no documentation available of a voluntary AMA form signed by the patient for medical record # 3.	E 161	#3 - Record Reviewed W/R Nurse on Duty 1/14. AMA form must be Signed prior to Discharge Reviewed 2/20/15 In Service 2/20/15 To Stress ascertain all proper Documentation must be Signed at Discharge	
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on observations during tour and staff interviews the facility staff failed to maintain equipment and supplies in a manner to ensure safety and the prevention of the transmission of infections. The findings include:	E 165	- IN Service - Counters & Cabnets Space were Reviewed. Clean Counters & Cabnets were Disinfected. Clean Counters & Cabnets ON 1 Side. NON STERILE Packs ON DIFFERENT WALL - STERILE 1 complete Side - NON STERILE 1 Complete and Different Side	3/30/15 3/30/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 7 1. Observations during tour of the facility on 02/05/2015 at 0844 revealed a decontamination ("scrub") area used to clean, sterilize, and store surgical instruments. Observation revealed a storage cabinet located above a countertop in the clean scrub room. Observation revealed the counter top was used to wrap clean surgical instruments for sterilization. Observation of the inside of the storage cabinet revealed 13 blue paper wrapped surgical instrument packs being stored on shelves. Observation of the packs revealed they were sealed with external sterilization indicator tape (tape used to indicate sterilization completed). Observation revealed 7 packs had external sterilization indicator tape indicating the packs had been steam sterilized in the autoclave (tape turned black). Observation revealed 6 packs had external sterilization indicator tape indicating the packs had not been sterilized (tape was white). Observation revealed the sterilized and non-sterilized packs were commingled together and stored on the same shelves. Interview during tour with Scrub Technician #1 revealed the storage cabinet was used to store sterilized surgical instrument packs. Interview revealed non-sterilized packs should not be stored in the cabinet. Interview revealed "I normally never store them together." Interview revealed she was unsure of who placed the non-sterilized packs in the clean storage cabinet. Interview during tour with Administrative Management Staff #1 confirmed the observations. 2. Observation during tour of the facility on 02/05/2015 at 1100 revealed a closet located in the recovery area's patient restroom. Observation revealed the closet door was secured with a keyed lock. Observation inside of the closet revealed portable medical gas	E 165	Organized Cabinet and Countertops. Will NOT Mix STERILE and NON STERILE Pack, will NOT be Commingled together. and STORED on SAME Shelves. We will Have (1) Separate Counter & Cabnet above FOR STERILE. (2) Separate Cabnet & Counter FOR NON STERILE. 2/20/15 Closet FOR NITROUS Oxide Tanks will be Separate. FROM other Supplies 3/1/15	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 8 cylinders being stored. Observation revealed five (5) full nitrous oxide cylinders, (1) empty nitrous oxide cylinder, (2) full oxygen cylinders, and (3) empty oxygen cylinders not separated by full or empty category. Observation revealed one chain across the front of the closet entry. Observation revealed the cylinders were standing up right and not secured in a rack or by individual chains. Observation revealed the medical gas cylinders were being stored with paper products (i.e. cups, paper towels) and cleaning chemicals (i.e. Lysol, Caviwipes, Clorox, Hand Soap), and ultra sound gel. Observation revealed no signage on the exterior closet door surface identifying the space as an oxygen/medical gas storage area. Interview during tour with a staff registered nurse revealed the closet was used to store oxygen and nitrous oxide cylinders, and cleaning supplies. Interview on 02/05/2014 at 1445 with Administrative Management Staff #1 confirmed the closet is used to store cleaning supplies, oxygen and nitrous oxide cylinders. Interview revealed the facility does not have a policy or procedure for storage of medical gases. 3. Observations during tour of the facility on 02/05/2015 at 1110 revealed 10 recliner chairs located in the recovery area. Observation revealed 7 out of 10 recliner chairs contained multiple various sized tears in the surface of the seat cushion. Interview with a staff registered nurse revealed the recliner chairs were used for patient recovery after surgical abortion procedures. Interview revealed the recliner chairs are wiped down with a disinfectant solution in between patient use. Interview revealed disposable blue absorption pads are placed on the seat cushions over the tears to try to prevent soiling. Interview confirmed 7 out of 10 recliner	E 165	a Special Rack has been ordered to Hold Tanks IN Closet IN a more Secure Manner. Due IN From Manufacter by 5/1/15. 5/1/15 ALL Other Paper Products, and Supplies, Cleaning Chemicals, Hand Soap lil Tnasound Gel etc. will be Stored IN a Separate Closet. 3/1/15 The Nitrous Oxide Tanks, are NOW IN Closet. by Themselves 3/1/15 (3) Recliner Chairs with Taped over Tears will be Replaced. and have been Ordered	

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	C 02/05/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 9 chairs contained tears in the seat cushions. Interview during tour with Administrative Management Staff #1 confirmed the observations. NC00102604 NC00103930	E 165	We have an Approximate Date of Delivery 5/30/15	

HF Acquisition Co. LLC

Banyan

Life-Saving Equipment, Medications and Training

Remit Payment To:
Dept. CH 14388
Palatine, IL 60055-4388

State License: 28443
DEA License:

Invoice	**INV1136363**
Ship Date	**2/10/2015**
Amount Due	**$ 129.29**
Page	**1 of 1**

MELVIN HENDERSON MD

Bill To Customer: 1012925
MELVIN HENDERSON MD
1919 GILLESPIE ST
ATTN:TAMMY
FAYETTEVILLE, NC 28306-3698

Ship To Customer: 1012925
CLARENCE J WASHINGTON MD
1919 GILLESPIE ST
ATTN:TAMMY
FAYETTEVILLE, NC 28306-3698
ATTN:TAMMY

PO Number	Salesperson ID	Payment Terms	Shipping Method	Kit Location	Kit No.
KMCA		NET ON RECEIPT	UPS GROUND		579

Ordered	Shipped	B/O	Item	Description	Lot/Serial	Exp. Date	Unit Price	Ext Price
1	1	0	KMCA	Keep Me Current Automatic			113.79	113.79
1	1	0	11-1015	VERAPAMIL 2ML 2.5MG/ML VIAL (SINGLE DOSE)	38309DK	02/01/2016		
2	2	0	11-107	ONDANSETRON 2ML 2MG/ML VIAL	034397	03/31/2016		
2	2	0	11-807	LIDOCAINE 2% 5ML LUER LOCK SYRINGE	38091DK	02/01/2016		
1	1	0	3895	BANYAN Environmental Recovery Envelope 8 1/2" x 11"	N/A	03/01/2015		
1	1	0	996	PDMA ELECTRONIC FEE				

IMPORTANT NOTICE: A credit cannot be issued for returned prescription drugs or kit orders. Per the FDA compliance policy guidance manual, we cannot warrant drug safety, identity, strength, quality or purity of medications after they have left our facility. Therefore we cannot accept any returns. Thank you for your understanding.

FINANCE CHARGES: Finance charges may be assessed on past due balances at a periodic rate of 1.5% per month (Annual Percentage Rate 18%). Customer shall be obligated to pay costs and expenses of collection, including reasonable attorney fees.

Subtotal	113.79
Shipping	15.50
Sales Tax	0.00
Total	129.29
Less Amount Rec'd	(0.00)
Total Amount Due	**129.29**

EIN: 27-0535896
DEA:
FL Permit: 23:2371
PHMF: FX60168802
PHWH: FX60109560

HF Acquisition Co, LLC
22316 70th Ave W Unit A
Mountlake Terrace, WA 98043
Tel: 800.351.4530

Email CustomerService@statkit.com
R20150210-1-Z1

For drug history: http://banyan.axwaysaas.com:9083/pedigreeGUI/login.jsp Login: banyaneped, Pwd: Banyan

Patient Drug Education

Pharmacy: Cape Fear Valley HS
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: HALLMARK CLINIC
1919 GILLESPIE ST
Fayetteville, NC 28306

Drug: AMINOPHYLLIN Rx: 843355 Date: 02/05/2015 Physician: MELVIN HENDERSON (910) 480-4880
GENERIC NAME: AMINOPHYLLINE (am-in-OFF-i-lin)

COMMON USES:
This medicine is a bronchodilator used to treat the symptoms of asthma, chronic bronchitis, and emphysema. It may also be used to treat other conditions as determined by your doctor.

HOW TO USE THIS MEDICINE:
Follow the directions for using this medicine provided by your doctor. THIS MEDICINE IS USUALLY GIVEN AS AN INFUSION at a hospital or clinic. THIS MEDICINE IS SOMETIMES USED AT HOME as an infusion. If you are using this medicine at home, a healthcare professional will provide you with detailed instructions. Ask any questions that you may have about this medicine or giving infusions. STORE THIS MEDICINE as directed by the prescription label. IF YOU MISS A DOSE OF THIS MEDICINE, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

CAUTIONS:
DO NOT INFUSE THIS MEDICINE FASTER THAN the rate recommend by your doctor. Exceeding the recommended rate may cause extreme dizziness, fainting, or irregular heart rate. If you experience dizziness, fainting, or irregular heart rate after using this medicine, check with your doctor. KEEP ALL DOCTOR AND LABORATORY APPOINTMENTS while you are taking this medicine. BEFORE YOU HAVE ANY MEDICAL OR DENTAL TREATMENTS OR SURGERY, tell the doctor or dentist that you are taking this medicine. AVOID LARGE AMOUNTS OF caffeine-containing foods and beverages, such as coffee, tea, cocoa, cola drinks, and chocolate. BEFORE YOU BEGIN TAKING ANY NEW MEDICINE, either prescription or over-the-counter, check with your doctor or pharmacist. FOR WOMEN: IF YOU PLAN ON BECOMING PREGNANT, discuss with your doctor the benefits and risks of using this medicine during pregnancy. THIS MEDICINE IS EXCRETED IN BREAST MILK. IF YOU ARE OR WILL BE BREAST-FEEDING while you are using this medicine, check with your doctor or pharmacist to discuss the risks to your baby.

POSSIBLE SIDE EFFECTS:
SIDE EFFECTS, that may go away during treatment, include nervousness, restlessness, or nausea. If they continue or are bothersome, check with your doctor. CHECK WITH YOUR DOCTOR AS SOON AS POSSIBLE if you experience stomach pain; diarrhea; black or tarry stools; difficulty sleeping; confusion; change in behavior; headache; fast or irregular heartbeat; dizziness; lightheadedness; fainting; muscle twitching; seizures; rapid breathing; or pain, redness, or swelling at the injection site. If you notice other effects not listed above, contact your doctor, nurse, or pharmacist. This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

BEFORE USING THIS MEDICINE:
Some medicines or medical conditions may interact with this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the- counter medicine that you are taking. DO NOT TAKE THIS MEDICINE if you are also taking certain medicine for high blood pressure or heart conditions (nonselective beta blockers). ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking barbiturates, cimetidine, erythromycin, fluvoxamine, lithium, mexiletine, birth control pills, rifampin, quinolone antibiotics, tacrine, thiabendazole, ticlopidine, troleandomycin, verapamil, zileuton, or medicine for seizures. Inform your doctor of any other medical conditions, allergies, pregnancy, or breast-feeding. Contact your doctor or pharmacist if you have any questions or concerns about taking this medicine.

OVERDOSE:
If overdose is suspected, contact your local poison control center or emergency room immediately. Symptoms of overdose may include fast or irregular heartbeat, nausea or vomiting, unusual nervousness or restlessness, agitation, irritability, headache, and seizures.

ADDITIONAL INFORMATION:
If your symptoms do not improve or if they become worse, check with your doctor. Carry an identification card at all times that says you are taking this medicine. DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS MEDICINE out of the reach of children. IF USING THIS MEDICINE FOR AN EXTENDED PERIOD OF TIME, obtain refills before your supply runs out.

(Patient Drug Education continued on next page...)

Pharmacy: **Cape Fear Valley HS**
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: **HALLMARK CLINIC**
1919 GILLESPIE ST
Fayetteville, NC 28306

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

Patient Drug Education

Pharmacy: Cape Fear Valley HS
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: HALLMARK CLINIC
1919 GILLESPIE ST
Fayetteville, NC 28306

Drug: EPINEPHRINE Rx: 843359 Date: 02/05/2015 Physician: MELVIN HENDERSON (910) 480-4880
GENERIC NAME: EPINEPHRINE (ep-i-NEF-rin)

COMMON USES:
This medicine is a sympathomimetic used for treating severe allergic reactions (eg, difficulty breathing; rash; hives; itching; tightness in the chest; swelling of the mouth, lips, or tongue) caused by insect stings or bites, foods, drugs, or other causes. It may also be used for other conditions as determined by your doctor.

HOW TO USE THIS MEDICINE:
Follow the directions for taking this medicine provided by your doctor. THIS MEDICINE IS USUALLY GIVEN as an injection at your doctor's office, hospital, or clinic. If you will be using this medicine at home, a health care provider will teach you how to use it. Be sure you understand how to use this medicine. Follow the procedures you are taught when you use a dose. Contact your health care provider if you have any questions. DO NOT USE THIS MEDICINE IF it contains particles, is cloudy or discolored, or if the vial is cracked or damaged. STORE THIS MEDICINE at room temperature, between 59 and 77 degrees F (15 and 25 degrees C). Store away from heat, moisture, and light. KEEP THIS PRODUCT, as well as syringes and needles, out of the reach of children and pets. IF YOU MISS A DOSE OF THIS MEDICINE, contact your doctor right away.

CAUTIONS:
DO NOT USE THIS MEDICINE IF you are allergic to any ingredient in this medicine, unless your doctor tells you otherwise. DO NOT INJECT THIS MEDICINE INTO the buttocks. It may not provide effective treatment of an allergic reaction. NEVER INJECT THIS MEDICINE INTO hands, fingers, feet, or toes. Doing so may cause a loss of blood flow and result in tissue damage to these areas. If you accidentally inject this medicine into any of these areas, seek immediate emergency medical attention. PATIENTS WITH PARKINSON DISEASE may notice a temporary worsening of symptoms (eg, uncontrolled muscle movements). If these symptoms persist, contact your doctor. BEFORE YOU BEGIN TAKING ANY NEW MEDICINES, either prescription or over-the-counter, check with your doctor or pharmacist. USE THIS MEDICINE WITH CAUTION in the ELDERLY; they may be more sensitive to its effects. FOR WOMEN: IF YOU BECOME PREGNANT, contact your doctor. You will need to discuss the benefits and risks of using this medicine while you are pregnant. IT IS NOT KNOWN IF THIS MEDICINE IS FOUND in breast milk. IF YOU ARE OR WILL BE BREAST-FEEDING while you use this medicine, check with your doctor. Discuss any possible risks to your baby. DIABETES PATIENTS - This medicine may raise your blood sugar. High blood sugar may make you feel confused, drowsy, or thirsty. It can also make you flush, breathe faster, or have a fruit-like breath odor. If these symptoms occur or persist, tell your doctor right away.

POSSIBLE SIDE EFFECTS:
SIDE EFFECTS that may occur while taking this medicine include anxiety; difficulty sleeping; dizziness; fearfulness; headache; nausea; nervousness; paleness; sweating; tremors; vomiting; or weakness. If they continue or are bothersome, check with your doctor. CONTACT YOUR DOCTOR IMMEDIATELY if you experience chest pain; fast or irregular heartbeat; or wheezing. AN ALLERGIC REACTION to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue. This is not a complete list of side effects. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA- 1088.

BEFORE USING THIS MEDICINE:
Some medicines or medical conditions may interact with this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the- counter medicine that you are taking. ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking alpha-blockers (eg, prazosin), beta- blockers (eg, propanolol), droxidopa, ergot alkaloids (eg, ergotamine), phenothiazines (eg, chlorpromazine), bromocriptine, furazolidone, linezolid, tricyclic antidepressants (eg, amitriptyline), antihistamines (eg, diphenhydramine), catechol-O-methyltransferase (COMT) inhibitors (eg, entacapone), digoxin, diuretics (eg, furosemide, hydrochlorothiazide), levothyroxine, medicines for irregular heartbeat (eg, quinidine), monoamine oxidase inhibitors (MAOIs) (eg, phenelzine), or guanethidine. DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including glaucoma, heart disease, chest pain, high blood pressure, blood vessel problems, diabetes, Parkinson disease, thyroid problems, mood or mental disorders, depression, asthma, irregular heartbeat, allergies (including sulfites), pregnancy, or breast-feeding. Contact your doctor or pharmacist if you

(Patient Drug Education continued on next page...)

have any questions or concerns about using this medicine.

OVERDOSE:
IF OVERDOSE IS SUSPECTED, contact your local poison control center or emergency room immediately. Symptoms may include chest pain; extreme paleness or coldness of the skin; fast or irregular heartbeat; one- sided weakness; severe headache or dizziness; or trouble breathing.

ADDITIONAL INFORMATION:
DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS PRODUCT, as well as syringes and needles, out of the reach of children and pets. Do not reuse needles, syringes, or other materials. Ask your health care provider how to dispose of these materials after use. Follow all local rules for disposal. CHECK WITH YOUR PHARMACIST about how to dispose of unused medicine.

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

Patient Drug Education

Pharmacy: Cape Fear Valley HS
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: HALLMARK CLINIC
1919 GILLESPIE ST
Fayetteville, NC 28306

Drug: NALBUPHINE Rx: 843360 Date: 02/05/2015 Physician: MELVIN HENDERSON (910) 480-4880
GENERIC NAME: NALBUPHINE (NAL-byoo-feen)

COMMON USES:
This medicine is a narcotic analgesic used to treat or prevent moderate to severe pain. It may also be used to treat other conditions as determined by your doctor.

HOW TO USE THIS MEDICINE:
This medicine is sometimes used at home as an injection. Before using this medicine, a healthcare professional will provide detailed instructions for appropriate use of this medicine. Ask any questions that you may have about this medicine or giving injections. STORE THIS MEDICINE as directed on the prescription label. IF YOU MISS A DOSE OF THIS MEDICINE and you are using it regularly, use it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not use 2 doses at once.

CAUTIONS:
DO NOT TAKE THIS MEDICINE IF YOU HAVE HAD A SEVERE ALLERGIC REACTION to morphine or hydromorphone (such as MS Contin, Roxanol, Dilaudid). A severe allergic reaction includes a severe rash, hives, breathing difficulties, or dizziness. If you have a question about whether you are allergic to this medicine or if a certain medicine contains morphine or hydromorphone, contact your doctor or pharmacist. IF YOU EXPERIENCE difficulty breathing; tightness of chest; swelling of eyelids, face, or lips; or if you develop a rash or hives, tell your doctor immediately. Do not take any more of this medicine unless your doctor tells you to do so. DO NOT EXCEED THE RECOMMENDED DOSE or take this medicine for longer than prescribed. Exceeding the recommended dose or taking this medicine for longer than prescribed may be habit-forming. BEFORE YOU HAVE ANY MEDICAL OR DENTAL SURGERY OR EMERGENCY TREATMENT, tell the doctor or dentist that you are taking this medicine. AVOID ALCOHOL while you are using this medicine. This medicine will add to the effects of alcohol and other depressants. DO NOT DRIVE, OPERATE MACHINERY, OR DO ANYTHING ELSE THAT COULD BE DANGEROUS until you know how you react to this medicine. Using this medicine alone, with other medicines, or with alcohol may lessen your ability to drive or to perform other potentially dangerous tasks. BEFORE YOU BEGIN TAKING ANY NEW MEDICINE, either prescription or over-the-counter, check with your doctor or pharmacist. FOR WOMEN: IF YOU PLAN ON BECOMING PREGNANT, discuss with your doctor the benefits and risks of using this medicine during pregnancy. IT IS UNKNOWN IF THIS MEDICINE IS EXCRETED in breast milk. IF YOU ARE OR WILL BE BREAST-FEEDING while you are using this medicine, check with your doctor or pharmacist to discuss the risks to your baby.

POSSIBLE SIDE EFFECTS:
SIDE EFFECTS that may occur while you are using this medicine include drowsiness, dizziness, constipation, or nausea. If they continue or are bothersome, check with your doctor. CHECK WITH YOUR DOCTOR AS SOON AS POSSIBLE if you experience vomiting, seizures, difficulty urinating, fainting, or weakness or fatigue. CONTACT YOUR DOCTOR IMMEDIATELY if you experience slowed breathing; slow or irregular heartbeat; severe or persistent weakness or fatigue; swelling of your throat or tongue; difficulty swallowing or breathing; or hoarseness. An allergic reaction to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, swelling, severe dizziness, or trouble breathing. If you notice other effects not listed above, contact your doctor, nurse, or pharmacist. This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

BEFORE USING THIS MEDICINE:
INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-counter medicine that you are taking. Inform your doctor of any other medical conditions, allergies, pregnancy, or breast-feeding.

OVERDOSE:
If overdose is suspected, contact your local poison control center or emergency room immediately. Symptoms of overdose may include sleepiness, restlessness, and general discomfort.

ADDITIONAL INFORMATION:
DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS MEDICINE out of the reach of children and away from pets. Dispose of properly after use.

(Patient Drug Education continued on next page...)

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

Patient Drug Education

Pharmacy: **Cape Fear Valley HS**
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: **HALLMARK CLINIC**
1919 GILLESPIE ST
Fayetteville, NC 28306

Drug: ADENOSINE Rx: 843361 Date: 02/05/2015 Physician: MELVIN HENDERSON (910) 480-4880
GENERIC NAME: ADENOSINE (a-DEN-oh-seen)

COMMON USES:
This medicine is an antiarrhythmic and a nucleoside used to treat certain types of irregular heartbeat. Certain brands of this medicine are used during a stress test of the heart. It may also be used for other conditions as determined by your doctor.

HOW TO USE THIS MEDICINE:
This medicine is administered as an injection at your doctor's office, hospital, or a clinic. Contact your health care provider if you have any questions. This medicine is handled and stored by a health care provider. You will not store it at home. Keep all medicines out of the reach of children and away from pets. IF YOU MISS A DOSE OF THIS MEDICINE, contact your doctor immediately.

CAUTIONS:
DO NOT TAKE THIS MEDICINE if you have had an allergic reaction to it or if you are allergic to any ingredient in this product. Laboratory and/or medical tests, including electrocardiogram (ECG) and blood pressure, may be performed to monitor your progress or to check for side effects. KEEP ALL DOCTOR AND LABORATORY APPOINTMENTS while you are using this medicine. VERY BAD AND SOMETIMES deadly heart problems (eg, irregular heartbeat) have happened after this drug was given. Discuss any questions or concerns with your doctor. AVOID CAFFEINE-CONTAINING foods and beverages, such as coffee, tea, cocoa, cola drinks, and chocolate before getting this drug. Talk with your doctor if you have questions. FOR WOMEN: IF YOU PLAN ON BECOMING PREGNANT, discuss with your doctor the benefits and risks of using this medicine during pregnancy. IF YOU ARE OR WILL BE BREAST-FEEDING while you are using this medicine, check with your doctor or pharmacist to discuss the risks to your baby.

POSSIBLE SIDE EFFECTS:
SIDE EFFECTS that may occur during treatment include flushing; headache; lightheadedness; dizziness; or stomach pain. If they continue or are bothersome, check with your doctor. CONTACT YOUR DOCTOR IMMEDIATELY if you experience seizures; severe dizziness or headache; shortness of breath or wheezing; chest pain; confusion; fainting; fast, slow, or irregular heartbeat; one-sided weakness; speech or vision problems; or throat, neck, or jaw pain.. AN ALLERGIC REACTION to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash; hives; itching; difficulty breathing; tightness in the chest or throat; swelling of the mouth, face, lips, or tongue. This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

BEFORE USING THIS MEDICINE:
Some medicines or medical conditions may interact with this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the- counter medicine that you are taking. ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking aminophylline, dipyridamole, methylxanthines (eg, theophylline, caffeine), beta- blockers (eg, metoprolol), digoxin, diltiazem, verapamil, or carbamazepine. DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including blood vessel problems, heart problems, low blood volume, or lung or breathing problems (eg, emphysema, bronchitis), allergies, pregnancy, or breast-feeding. Tell your doctor if you have a history of seizures. USE OF THIS MEDICINE IS NOT RECOMMENDED if you have certain breathing problems (eg, asthma), or if you have certain heart problems (eg, second or third degree heart block, sick sinus syndrome) and you do not have an artificial pacemaker. Contact your doctor or pharmacist if you have any questions or concerns about taking this medicine.

OVERDOSE:
If overdose is suspected, contact your local poison control center or emergency room immediately.

ADDITIONAL INFORMATION:
DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. Do not reuse needles, syringes, or other materials. Dispose of properly after use. Ask your doctor, nurse, or pharmacist to explain local regulations for selecting an appropriate container and properly disposing of the container when it is full. CHECK WITH YOUR PHARMACIST about how to dispose of unused medicine.

(Patient Drug Education continued on next page...)

Pharmacy: Cape Fear Valley HS
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: HALLMARK CLINIC
1919 GILLESPIE ST
Fayetteville, NC 28306

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

Patient Drug Education

Pharmacy: Cape Fear Valley HS
Valley Pharmacy, 1638 Owen Drive
Fayetteville, NC 28304
(910) 615-7895

Patient: HALLMARK CLINIC
1919 GILLESPIE ST
Fayetteville, NC 28306

Drug: EPINEPHRINE Rx: 843362 Date: 02/05/2015 Physician: MELVIN HENDERSON (910) 480-4880
GENERIC NAME: EPINEPHRINE (ep-i-NEF-rin)

COMMON USES:
This medicine is a sympathomimetic used for treating severe allergic reactions (eg, difficulty breathing; rash; hives; itching; tightness in the chest; swelling of the mouth, lips, or tongue) caused by insect stings or bites, foods, drugs, or other causes. It may also be used for other conditions as determined by your doctor.

HOW TO USE THIS MEDICINE:
Follow the directions for taking this medicine provided by your doctor. THIS MEDICINE IS USUALLY GIVEN as an injection at your doctor's office, hospital, or clinic. If you will be using this medicine at home, a health care provider will teach you how to use it. Be sure you understand how to use this medicine. Follow the procedures you are taught when you use a dose. Contact your health care provider if you have any questions. DO NOT USE THIS MEDICINE IF it contains particles, is cloudy or discolored, or if the vial is cracked or damaged. STORE THIS MEDICINE at room temperature, between 59 and 77 degrees F (15 and 25 degrees C). Store away from heat, moisture, and light. KEEP THIS PRODUCT, as well as syringes and needles, out of the reach of children and pets. IF YOU MISS A DOSE OF THIS MEDICINE, contact your doctor right away.

CAUTIONS:
DO NOT USE THIS MEDICINE IF you are allergic to any ingredient in this medicine, unless your doctor tells you otherwise. DO NOT INJECT THIS MEDICINE INTO the buttocks. It may not provide effective treatment of an allergic reaction. NEVER INJECT THIS MEDICINE INTO hands, fingers, feet, or toes. Doing so may cause a loss of blood flow and result in tissue damage to these areas. If you accidentally inject this medicine into any of these areas, seek immediate emergency medical attention. PATIENTS WITH PARKINSON DISEASE may notice a temporary worsening of symptoms (eg, uncontrolled muscle movements). If these symptoms persist, contact your doctor. BEFORE YOU BEGIN TAKING ANY NEW MEDICINES, either prescription or over-the-counter, check with your doctor or pharmacist. USE THIS MEDICINE WITH CAUTION in the ELDERLY; they may be more sensitive to its effects. FOR WOMEN: IF YOU BECOME PREGNANT, contact your doctor. You will need to discuss the benefits and risks of using this medicine while you are pregnant. IT IS NOT KNOWN IF THIS MEDICINE IS FOUND in breast milk. IF YOU ARE OR WILL BE BREAST-FEEDING while you use this medicine, check with your doctor. Discuss any possible risks to your baby. DIABETES PATIENTS - This medicine may raise your blood sugar. High blood sugar may make you feel confused, drowsy, or thirsty. It can also make you flush, breathe faster, or have a fruit-like breath odor. If these symptoms occur or persist, tell your doctor right away.

POSSIBLE SIDE EFFECTS:
SIDE EFFECTS that may occur while taking this medicine include anxiety; difficulty sleeping; dizziness; fearfulness; headache; nausea; nervousness; paleness; sweating; tremors; vomiting; or weakness. If they continue or are bothersome, check with your doctor. CONTACT YOUR DOCTOR IMMEDIATELY if you experience chest pain; fast or irregular heartbeat; or wheezing. AN ALLERGIC REACTION to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue. This is not a complete list of side effects. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA- 1088.

BEFORE USING THIS MEDICINE:
Some medicines or medical conditions may interact with this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the- counter medicine that you are taking. ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking alpha-blockers (eg, prazosin), beta- blockers (eg, propanolol), droxidopa, ergot alkaloids (eg, ergotamine), phenothiazines (eg, chlorpromazine), bromocriptine, furazolidone, linezolid, tricyclic antidepressants (eg, amitriptyline), antihistamines (eg, diphenhydramine), catechol-O-methyltransferase (COMT) inhibitors (eg, entacapone), digoxin, diuretics (eg, furosemide, hydrochlorothiazide), levothyroxine, medicines for irregular heartbeat (eg, quinidine), monoamine oxidase inhibitors (MAOIs) (eg, phenelzine), or guanethidine. DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including glaucoma, heart disease, chest pain, high blood pressure, blood vessel problems, diabetes, Parkinson disease, thyroid problems, mood or mental disorders, depression, asthma, irregular heartbeat, allergies (including sulfites), pregnancy, or breast-feeding. Contact your doctor or pharmacist if you

(Patient Drug Education continued on next page...)

have any questions or concerns about using this medicine.

OVERDOSE:
IF OVERDOSE IS SUSPECTED, contact your local poison control center or emergency room immediately. Symptoms may include chest pain; extreme paleness or coldness of the skin; fast or irregular heartbeat; one- sided weakness; severe headache or dizziness; or trouble breathing.

ADDITIONAL INFORMATION:
DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS PRODUCT, as well as syringes and needles, out of the reach of children and pets. Do not reuse needles, syringes, or other materials. Ask your health care provider how to dispose of these materials after use. Follow all local rules for disposal. CHECK WITH YOUR PHARMACIST about how to dispose of unused medicine.

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0007	A. BUILDING: _____ B. WING _____	11/10/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HALLMARK WOMEN'S CLINIC	1919 GILLESPIE STREET FAYETTEVILLE, NC 28306

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS An unannounced, onsite complaint and recertification survey was conducted November 9-10, 2015. No deficiencies were cited. NC00111857	E 000		

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt, Director

November 16, 2015

Tammy Chalmers, CEO
Clarence J. Washington, M.D.
1919 Gillespie Street
Fayetteville, NC 28306

RE: State Recertification Survey and Complaint Investigation

Dear Ms. Chalmers:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the complaint investigation and recertification survey conducted November 9, 2015 through November 10, 2015. The purpose of conducting the survey was to evaluate the facility's compliance with the North Carolina Rules for the certification of Abortion Clinics.

As discussed in the exit conference, 0 of 3 allegations were unsubstantiated and there were no deficiencies cited as a result of the survey. The State Agency will be referring this complaint to the NC Medical Board for review.

Should you have questions concerning the investigation or survey, please do not hesitate to call me at (919) 855-4620.

Sincerely,

Lynn Ethridge, RN, BSN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Acute and Home Care Licensure and Certification Section
http://www.ncdhhs.gov/dhsr/
Phone: (919) 855-4620 Fax: (919) 715-3073
Mailing Address: 2712 Mail Service Center Raleigh, North Carolina 27669-2712

Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
An Equal Opportunity / Affirmative Action Employer

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	110748	A. BUILDING: _____ B. WING _____	06/12/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTH DURHAM WOMEN'S HEALTH, INC	400-B CRUTCHFIELD ST DURHAM, NC 27704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS An announced initial licensure survey was conducted on 06/12/2015. No deficiencies cited. State Agency recommends licensure effective 06/12/2015.	E 000		

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

June 29, 2015

Jodi Robertson, Sole Director/President
North Durham Women's Health, Inc
400-B Crutchfield St
Durham, NC 27704

RE: State Licensure Survey

Dear Ms. Robertson:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the State Licensure Survey conducted June 12, 2015. The purpose of conducting the survey was to evaluate the facility's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortion.

As discussed in the exit conference, there were no deficiencies cited as a result of the survey and the State Agency recommended Licensure effective 06/12/2015. Should you have questions concerning the survey, please do not hesitate to call me at (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

March 20, 2014

Janet Colm, CEO
Planned Parenthood Of Central North Carolina
1765 Dobbins Road
Chapel Hill, NC 27514

Re: State Licensure and Recertification Survey

Dear Ms. Colm,

Thank you and your staff for the assistance and cooperation extended during the state licensure and recertification survey at Planned Parenthood of Central North Carolina in Chapel Hill, NC from March 5, 2014 through March 6, 2014. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Licensing Abortion Clinics. As discussed at the exit conference, state licensure deficiencies were identified with respect to 10A-NCAC-14E.0314 Cleaning of Materials and Equipment and 10A-NCAC-14E.0315 Housekeeping.

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.

(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and

(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed State Form with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

RN, MSN

Anita Myers, RN, MSN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Enclosures: State Form - Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

4/14/14 JM

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on facility policy review, manufacturer's recommendations review, observation and staff interview, the facility staff failed to ensure disinfection of the vaginal ultrasound probe was performed after each use and according to manufacturer's recommendations for 1 of 3 ultrasound machines observed. The findings include: Review of current "Ultrasound Probe Disinfection" policy revised 08/2013, revealed "Describe procedure to be utilized after/between each use: I. Vaginal: High Level Disinfection: ...Soak in high level disinfectant (...Cidex [disinfectant]...for 12 minutes)..." Review of the "Ultrasound Users Manual," page 17, provided by administrative management staff revealed "...it is very important...to minimize the risk of disease transmission by using barriers and through proper processing between patients. Risk of Infection: ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination...Adequate cleaning and disinfection	E 165	PPCNC's current facility policy and procedure is consistent with safety standards including with manufacturer's instructions for ultrasound probe disinfection between patient uses. The indicated machine (in Procedure Room A) is primarily used for intraoperative ultrasound guidance via use of the abdominal probe, which is properly disinfected with a germicidal wipe. When used, it is rarely used for transvaginal indications. The vaginal probe is always covered with a new disposable sheath prior to use and the probe processing utilizes a chemical soak that is tested daily to achieve high level disinfection between each patient use. In response to feedback provided during the March 6, 2014 site visit and per 10A-14E.0314(a),	3/13/2014

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: CEO — TITLE — (X6) DATE: 4/7/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 1 are necessary to prevent disease transmission...Disinfecting probes: Perform After Each Use: Ultrasound probes can be disinfected using liquid chemical germicides ...Place the cleaned and dried probe in contact with the germicide for the time specified by the germicide manufacturer. High-level disinfection is recommended for surface probes and is required for endocavitary and intraoperative probes..." Observation on 03/06/2014 at 0930 during tour of procedure room "A" revealed an Ultrasound Machine with a vaginal probe. Observation revealed the probe was uncovered. Observation of the machine revealed no documentation of date and time the vaginal probe was last disinfected. Interview during tour with the HCA (health care assistant) revealed the probe is disinfected once a day in the morning prior to the start of the scheduled procedures. Interview revealed the process for disinfecting is soaking for 12 minutes in Cidex. Continued interview revealed the vaginal probe is wiped clean with a germicidal agent after each patient use, but it is not disinfected in Cidex but once a day. Interview confirmed the vaginal probe was not disinfected after each patient use. Interview confirmed the facility staff failed to follow the facility policy and manufacturer's recommendations.	E 165	the procedure followed in Room A now mirrors those followed in the other exam rooms to make clear and certain that all machines follow the same maintenance protocol regardless of frequency of use. This protocol includes the following steps: • Wipe gel off with a wet wipe containing only soap and water or with soap and water. • Soak in high level disinfectant per manufacturer's instructions (e.g. Cidex® OPA for 12 minutes). • Wipe with a wet wipe and allow to air dry. • Cover with a new sheath prior to next use. Additionally, the Health Center Manager has conducted a retraining of abortion services staff to ensure understanding of the policy and procedure regarding disinfection of ultrasound probes. The Clinical Trainer will ensure that this policy and procedure is incorporated into training and competency testing for future hires. Finally, the Health Center Manager will ensure that existing monthly QA checks include a review of the ultrasound disinfection procedure in Procedure Room A.	3/13/2014 Ongoing Monthly
E 166	.0315 HOUSEKEEPING 10A-14E .0315 Abortion clinics shall meet the standards for sanitation as required by the Division of Environmental Health in the rules and regulations governing the sanitation of private hospitals, nursing and rest homes, sanitariums, sanatoriums, and	E 166		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 166	Continued From page 2 educational and other institutions, 10 NCAC 10A, with special emphasis on the following: (1) There must be cleaning of such a frequency as to maintain the floors, walls, woodwork and windows in a manner to minimize the spread of dust particles in the atmosphere. Accumulated waste material must be removed at least daily. (2) The premises must be kept free from rodents and insect infestation. (3) Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. (4) Linen which comes directly in contact with the patient shall be provided as needed for each individual patient. No such linen shall be interchangeable from one patient to another before being properly cleaned, sterilized, or laundered. This Rule is not met as evidenced by: Based on facility policy review, housekeeping contract review, observations and staff interviews, the facility staff failed to maintain the procedure room floors in a clean and sanitary manner. The findings include: Review of current "Environmental Cleaning" Policy dated 08/2013 revealed "A contracted janitorial service performs general housekeeping tasks, including thorough cleaning of floors..., three times per week." Review of a "Cleaning Contract" signed 05/13/2013 revealed "Areas to be serviced:...Exam Rooms...Work Schedule 2 X	E 166	The procedure room floors have been refurbished to remove rust spots and dirt stains and a "strip and wax" has been scheduled for Saturday, March 29 to improve overall appearance. 3/29/2014 As per 10A-14E.0315, PPCNC's contract with our janitorial service has been revised to include mopping of procedure room floors after each	3/11/2014 3/21/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 166	Continued From page 3 (times) per week ...Floor Work: ...damp mop all finished floors with neutral cleaner - weekly ..." Review on 03/06/2014 of the contracted janitorial service's "Recommended Work Schedule: 2 - 3 visits per week" revealed "Nightly Services: All tile floors swept and damp mopped with disinfectant..." Observations during tour on 03/06/2014 at 0930 of procedure room "A", revealed rust and dirt stains on the floor at the head and foot of the procedure table. Observation of procedure room "B" revealed rust and dirt stains on the floor at the head and foot of the procedure table. Continued observation revealed dust and dirt particles on the floor of procedure room "B". Interview during tour with the Center Manager revealed abortion procedures are performed in procedure rooms "A" and "B" on Thursday, Friday, and Saturday. Interview revealed she had concerns that the floors, looked "unclean" especially the rust. Interview revealed the floors are not mopped between procedures. Interview revealed the procedure room floors are mopped three times a week by a contracted janitorial service on Tuesday, Thursday, and Saturday. Interview confirmed no mopping of the procedure room floors are done on Fridays after the scheduled procedures are completed. Interview on 03/06/2014 at 1300 with the Vice President of Patient Care Services revealed the facility staff does not mop floors between patients. Interview revealed procedures are scheduled in the procedure rooms on Monday, Tuesday and Thursday through Saturday. Interview revealed non-abortion procedures are performed on Monday and Tuesday. Interview revealed mopping of the procedure rooms are	E 166	day the room is utilized for patient care. The Health Center Manager will ensure that existing monthly QA checks include an assessment of effectiveness of cleaning services and will report any deficiencies to the Facilities Manager to immediately address with vendor.	Ongoing Monthly

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	03/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 166	Continued From page 4 done by the contracted janitorial staff only on Tuesday, Thursday, and Saturday.	E 166		

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 24, 2015

Elizabeth Dicker, Health Center Manager/Regional Director
Planned Parenthood Of Central North Carolina
1765 Dobbins Road
Chapel Hill, NC 27514

Re: Recertification Survey

Dear Ms. Dicker,

Thank you and your staff for the assistance and cooperation extended during the Recertification survey at Planned Parenthood Of Central North Carolina in Chapel Hill, NC, June 25, 2015. The survey was conducted in order to determine the facility's compliance with the Medicare Conditions of Participation for North Carolina Rules Governing the Certification of Clinics for Abortion . As a result of the survey, deficiencies were identified with respect to .0304 Admissionand Discharge and .0306 Health Screening for Physicians.

Enclosed please find STATE Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies should be submitted and include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form CMS 2567, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

Enclosures: CMS 2567 Statement of Deficiencies

AUG 12 2015

PRINTED: 07/24/2015
FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

V 8/17/2015
CAB

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	.0304(D) ADMISSIONS AND DISCHARGE 10A-14E .0304 (d) Following admission and prior to obtaining the consent for surgery required by Rule .0305(a) of this Section, representatives of the clinic's management shall provide to each patient the following information: (1) A fee schedule and any extra charges routinely applied, (2) The name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included; (3) Instructions for post-procedure emergencies as outlined in Rule .0313(d) of this Section; (4) Grievance procedures a patient may follow if dissatisfied with the care and services rendered; and (5) The telephone number of the Complaints Investigation Branch of the Division. This Rule is not met as evidenced by: Based on closed medical record review and administrative staff interview revealed prior to obtaining the consent for an Abortion Procedure the clinic staff failed to inform if the attending physician had hospital admitting privileges or in the absence of admitting privileges a statement to that effect in 5 of 7 Abortion procedures reviewed ((#1, #2, #3, #4 and #6) and failed to provide instructions for post-procedure emergencies in 7 of 7 Abortion procedures reviewed (#4, #5, #2, #7 #6, #1 and #3). The findings include:	E 136	Planned Parenthood South Atlantic's policy and procedure is that the attending physician is reviewed (with the patient) during the signing of 24 hour consent document. If, for any reason, the physician providing the abortion services changes, then the health center staff provides that information during the patient education and documents that information on the 24 hour consent form. Findings from the state survey identified a gap in training. Health center staff received retraining in policy and procedure on August 6, 2015. The Regional Director will conduct a sample audit of twenty consent forms to ensure compliance to be completed by August 31, 2105. It is Planned Parenthood South Atlantic's practice to review emergency instructions during the patient education session during which risks and benefits are reviewed and informed consent is obtained. As a result of this survey, Planned Parenthood South Atlantic- Chapel Hill is changing its practice to include after care instructions in every abortion patient's information packet given at check-in. Additionally, Planned Parenthood South Atlantic is introducing a statewide	8/31/15 8/24/15

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Vice President of Patient Services 8/11/15

RECEIVED AUG 17 2015 gs

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 1 1. Medical record review of patient #4 revealed the patient had a surgical abortion procedure (SAB) on 2015. Review of the record did not reveal any documentation the attending physician had hospital admitting privileges. Medical record review did not reveal documentation if the physician did not have hospital admitting privileges. Medical record review did not reveal any documentation the patient was provided instructions for post-procedure emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent of the attending physician having hospital admitting privileges and no documentation of instructions for post-procedure emergencies . The interview revealed the Form used to obtain the information if the physician has or does not have admission privileges is pre printed with the Medical Directors name only. The interview revealed there is no documentation of the physician performing the procedure has or does not have admission privileges. The interview revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure. 2. Medical record review of patient #5 revealed the patient had a medical abortion procedure (MAB) on /2015. Review of the record did not reveal any documentation the attending physician had hospital admitting privileges. Medical record review did not reveal documentation if the physician did not have hospital admitting privileges. Medical record review did not reveal any documentation the patient was provided instructions for	E 136	Abortion Patient & Physician Informed Consent document which includes patient acknowledgement and documentation of receipt of after care instructions prior to consent for abortion. This document will be introduced into practice on August 24, 2015, after North Carolina state-wide training of health care staff is completed. The Regional Director will conduct a sample audit of twenty medical records using the Abortion Patient & Physician Informed Consent document by August 31, 2105.	8/24/15 8/31/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 2 post-procedure emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent of the attending physician having hospital admitting privileges and no documentation of instructions for post-procedure emergencies . The interview revealed the Form used to obtain the information if the physician has or does not have admission privileges is pre printed with the Medical Directors name only. The interview revealed there is no documentation of the physician performing the procedure has or does not have admission privileges. The interview revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure. 3. Medical record review of patient #2 revealed the patient had a surgical abortion procedure (SAB) on /2015. Review of the record did not reveal any documentation the attending physician had hospital admitting privileges. Medical record review did not reveal documentation if the physician did not have hospital admitting privileges. Medical record review did not reveal any documentation the patient was provided instructions for post-procedure emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent of the attending physician having hospital admitting privileges and no documentation of instructions for post-procedure emergencies . The interview revealed the Form used to obtain the information	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 3 if the physician has or does not have admission privileges is pre printed with the Medical Directors name only. The interview revealed there is no documentation of the physician performing the procedure has or does not have admission privileges. The interview revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure. 4. Medical record review of patient 7 revealed the patient had a surgical abortion procedure (SAB) on /2015. Review of the record did not reveal any documentation the attending physician had hospital admitting privileges. Medical record review did not reveal documentation if the physician did not have hospital admitting privileges. Medical record review did not reveal any documentation the patient was provided instructions for post-procedure emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent of the attending physician having hospital admitting privileges and no documentation of instructions for post-procedure emergencies . The interview revealed the Form used to obtain the information if the physician has or does not have admission privileges is pre printed with the Medical Directors name only. The interview revealed there is no documentation of the physician performing the procedure has or does not have admission privileges. The interview revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure.	E 136		

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTI	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 4 5. Medical record review of patient #6 revealed the patient had a surgical abortion procedure (SAB) on /2015. Review of the record did not reveal any documentation the attending physician had hospital admitting privileges. Medical record review did not reveal documentation if the physician did not have hospital admitting privileges. Medical record review did not reveal any documentation the patient was provided instructions for post-procedure emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent of the attending physician having hospital admitting privileges and no documentation of instructions for post-procedure emergencies . The interview revealed the Form used to obtain the information if the physician has or does not have admission privileges is pre printed with the Medical Directors name only. The interview revealed there is no documentation of the physician performing the procedure has or does not have admission privileges. The interview revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure. 6. Medical record review of patient #1 revealed the patient had a surgical abortion procedure (SAB) on /2015. Review of the record did not reveal any documentation the attending physician had hospital admitting privileges. Medical record review did not reveal documentation if the physician did not have hospital admitting privileges. Medical record review did not reveal any documentation the patient was provided post-procedure instructions	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORT	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 5 for emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent of the attending physician having hospital admitting privileges and no documentation of instructions for post-procedure emergencies . The interview revealed the Form used to obtain the information if the physician has or does not have admission privileges is pre printed with the Medical Directors name only. The interview revealed there is no documentation of the physician performing the procedure has or does not have admission privileges. The interview revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure. 7. Medical record review of patient #3 revealed the patient had a medical abortion procedure (MAB) on 2015. Medical record review did not reveal any documentation the patient was provided instructions for post-procedure emergencies prior to obtaining consent. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed revealed instructions for post-procedure emergencies are not provided to the patients prior to obtaining consent and are provided in the recovery area after the procedure.	E 136		
E 149	.0306(D) PERSONNEL RECORDS 10A-14E .0306 (d) The governing authority shall be responsible for implementing health standards for employees, as well as contractual employees, which are consistent with	E 149	The referenced staff are primarily employed at a state tertiary care center that uses risk-based screening policy for TB screening that we accepted. This risk-based policy does not require TB testing. PPSAT will amend our policy of annual TB testing to include acceptance of risk-based screening from state regulated institutions by August 24, 2015.	8/24/15

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0032	A. BUILDING: _____ B. WING _____	06/25/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NORTH	1765 DOBBINS ROAD CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 149	Continued From page 6 recognized professional practices for the prevention and transmission of communicable diseases. This Rule is not met as evidenced by: Based on credential file reviews and staff interview the clinic failed to have testing for TB per the clinic policy in 2 of 4 Physician credential files reviewed (#2 and #3). The findings include: 1. Review of credential file for Physician #2 revealed no documentation of TB testing. Interview with the Health Center Manager on 06/25/2015 at 1530 revealed there was no documentation available for TB testing for Physician #2. The interview revealed the clinic's policy is annual testing. 2. Review of credential file for Physician #3 revealed no documentation of TB testing. Interview with the Health Center Manager on 06/25/2015 at 1530 revealed there was no documentation available for TB testing for Physician #2. The interview revealed the clinic's policy is annual testing.	E 149		

REC'D APR 22 2014

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 127	.0206(4) ELEMENTS AND EQUIPMENT 10A-14E . 0206 The physical plant shall provide appropriate elements and equipment to carry out functions of the facility with the following minimum requirements: (4) Each facility and its grounds shall be maintained to minimize hazards and enhance safety for staff and patients. Buildings systems and medical equipment must have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure satisfactory operation. This Rule is not met as evidenced by: Based on observations during tour, and staff interview the facility staff failed to maintain the physical plant and equipment in a manner to ensure hazards were minimized to enhance patient and staff safety. The findings include: *Observations during tour on 04/01/2014 at 1223* of the facility revealed the following: 1. In Surgical Suite #1 - the floor surface covering had an approximate 3-4 feet long linear crack with exposed concrete in the center of the room extending from the cabinets outward towards the surgical procedure table; an approximate 3-4 inch tear was in the protective covering of the surgical procedure table; Multiple holes in the wall at the head of the surgical procedure table with exposed dry wall. In Surgical Suite #2 - the floor surface covering had multiple tears/rips/holes of various sizes with	E 127	E127 1. Floors in both surgical suites have been temporarily patched. Permanent repairs have been scheduled and will be completed by May 15. The cushions on both exam tables have been removed and are being repaired. This will be completed by 4/22.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE: VP Operations

(X6) DATE: 4/18/14

STATE FORM 6899 8VZJ11 If continuation sheet 1 of 11

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 127	Continued From page 1 exposed concrete; an approximately 3-4 inch tear in the protective covering of the surgical procedure table. Interview during tour with facility staff revealed the two Surgical Suite's were available for patient procedures. Interview confirmed the above findings. 2. Observation during tour on 04/01/2014 at 1223 of the facility revealed one (1) steam autoclave machine located in the POC Lab/Reprocessing Area. Review of current facility policy "Infection Prevention Manual" reviewed October 2013/Implemented November 2013, revealed, page 5-9 "All sterilizers must be monitored at least once a week with commercial spore testing strips ..." Review of the "QC (Quality Control) Log: Daily/Weekly Spore Testing, Autoclave" from November 01, 2013 to April 01, 2014 revealed Spore Testing was performed on the following dates: 1. 11/14/2013; 2. 11/25/2013; 3. 12/02/2013; 4. 12/12/2013; 5. 12/16/2013; 6. 01/16/2014; 7. 02/11/2014; 8. 02/24/2014; 9. 03/18/2014; and 10. 03/31/2014. Review confirmed documentation of QC Spore Testing performed only on 10 out of 22 weeks from 11/01/2013 to 04/01/2014. Interview on 04/02/2014 at 0930 with Clinic Management Staff revealed the staff are to perform weekly biological (spore) testing. Interview revealed the results are to be documented on the QC log. Interview revealed the autoclave machine is used to sterilize surgical abortion trays, intrauterine device supplies, and speculums. Interview confirmed the autoclave was used on 04/01/2014 to reprocess a surgical	E 127	We have appointed a new Regional Director who will make bi-weekly site visits and will inspect the physical plant at each visit to make sure that all of its elements are in good repair and working order. Additionally, the VP for Operations, the Medical Director, and the Facilities Coordinator will make monthly visits and include this inspection in their onsite review. 2. Immediately upon discovering the autoclave machine was not undergoing quality testing on the established schedule, staff was immediately retrained on April 2nd to perform weekly spore testing on the autoclave. The new Regional Director will examine the log during bi-weekly visits to ensure that operations meet the highest standards.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 127	Continued From page 2 abortion tray. Interview confirmed the facility staff failed to follow the policy. 3. Review of current facility policy "Infection Prevention Manual" reviewed October 2013/Implemented November 2013, revealed, page 4-16 "Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use. ... Follow manufacturer's expiration date, located on vial or package insert. In the absence of an expiration date, the penetrated vial must be discarded after 28 days. Date all opened/penetrated vials ..." Observation during tour on 04/01/2014 at 1223 of the facility revealed a cabinet located above the sink/counter top in the POC Lab/Sterile Reprocessing area. Observation of the cabinet revealed a keyed lock on the cabinet door. Observation revealed the cabinet was unlocked and easily opened by the surveyor. Observation of the contents of the cabinet revealed medications being stored. Observation revealed one (1) opened multidose 50 milliliter (ml) vial of Lidocaine 1%, with no date opened on the label; one (1) opened 30 ml multidose vial of Lidocaine 2% with epinephrine, with an opened date of 01/02/2014 (90 days prior) written on the label; and (1) opened 50 ml single dose vial of Sodium Bicarbonate 8.4 %, with no date opened on the label and labeled "Good for 30 Days." Interview during tour with facility staff revealed the cabinet was used to store medications. Interview revealed the cabinet should be locked. Interview revealed multidose vials are good for 30 days. Interview revealed the staff member was unaware multidose vials were to be discarded in 28 days. Interview revealed all three of the medications were used for multiple doses. Interview revealed	E 127	3. It is PPHS's policy to keep medicine in a locked cabinet at all times when not in use. The staff was immediately (4/2/14) re-trained to keep the cabinet locked at all times when not in use. Staff training on multi dose vs single dose medications will occur by 4/25/14. An improved label system is being implemented that indicates the date the vial was opened and that multi-use vials will be discarded after 28 days. The new Regional Director will manually inspect all medications at each bi-weekly visit to make sure they are labelled and used correctly.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 127	Continued From page 3 the staff member was unaware the Sodium Bicarbonate vial was labeled as single dose only.	E 127	E141	
E 141	.0305(E) MEDICAL RECORDS 10A-14E .0305 (e) The facility shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least patient name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, and date and time of procedure. This Rule is not met as evidenced by: Based on clinic log reviews and staff interviews the clinic staff failed to maintain a daily procedure log containing estimated length of gestation, procedure type and the time of the procedure. The findings include: Review of the clinic's daily procedure log for January 2014 - March 2014 revealed the following omissions on the log: 03/19/2014 - no estimated length of gestation documented for any patient 03/15/2014 - no estimated length of gestation and time of procedure documented for any patient 03/05/2014 - no estimated length of gestation and time of procedure documented for any patient 02/26/2014 - no estimated length of gestation and time of procedure documented for 11 of 17 patients 02/19/2014 - no estimated length of gestation and time of procedure documented for any patient	E 141	While PPHS's medical records are complete, some staff was not following PPHS protocol to fully complete the Procedure Log which provides information to the state. Immediately following the inspection (4/3/14) the staff was re-trained on the correct way to complete the Procedure Log. Senior staff inspected the logs following surgical procedures on 4/9 and 4/12 and verified that the logs were completed in in their entirety with the columns for EGA, time of service, and type of service being completed. New oversight protocols have been instituted to ensure ongoing log accuracy and new Regional Director was put into place. Quality assurance oversight includes week review by the Director of Revenue Cycle and the new Regional Director will conduct on-site inspections of the logs bi-weekly. Any discrepancies will be immediately reported to the VP for Operations to ensure the highest standards are met. Additionally, the Regional Director will conduct on-site inspections of these at her bi-weekly visits.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 141	Continued From page 4 02/15/2014 - no estimated length of gestation and time of procedure documented for any patient 02/08/2014 -no estimated length of gestation and time of procedure documented for any patient 02/05/2014 - no estimated length of gestation and time of procedure documented for any patient 02/01/2014 - no estimated length of gestation, type of procedure and time of procedure documented for any patient 01/22/2014 - no estimated length of gestation, type of procedure and time of procedure documented for any patient 01/15/2014 - no estimated length of gestation for any patient, no type of procedure for 3 of 15 patients and no time of procedure for 10 of 15 patients 01/08/2014 - no estimated length of gestation and type of procedure for any patient, no time of procedure for 1 of 12 patients Interview on 04/01/2014 at 1330 with administrative staff revealed, "we have had a high turnover of staff. We started trying to get everything on the log on March 26th (2014)". Interview confirmed the daily procedure log did not contain all the required elements, including estimated length of gestation, type of procedure and time of procedure.	E 141		
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different	E 165		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 5 patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on policy reviews, observations during tour and staff interviews, the facility staff failed to ensure all supplies and equipment was cleaned, handled, and stored in a manner to prevent the transmission of infection. The findings revealed: Review of current facility policy "Infection Prevention Manual" reviewed October 2013/Implemented November 2013, revealed, page 5-3 "Reprocessing Area must be designated areas within the Health Center. Reprocessing Areas will be divided into two to three ... areas to accomplish the functions of decontamination, assembly and sterile processing, and if space permits, sterile storage. The area must be labeled 'Dirty', 'Clean' and 'Sterile'. ... Clean items are received in the assembly and packaging area from the decontamination area and are then assembled and prepared for issue, storage, or further processing (like sterilization). ... These areas will be set up to flow from dirty to clean to sterile, and to prevent cross-contamination." Review of current facility policy "Infection Prevention Manual" reviewed October 2013/Implemented November 2013, revealed, page 4-13 "All clean linen must be kept covered at all times before use."	E 165		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 6 Review of current facility policy "Infection Prevention Manual" reviewed October 2013/Implemented November 2013, revealed, page 5-9 "Procedure: for storage of sterile supplies ... Store sterile supplies 8 to 10 inches from the floor ... Do not store supplies where there is cross-traffic. ..." Observations during tour on 04/01/2014 at 1223 of the facility revealed the following: 1. In the Secondary Recovery/Waiting area - twenty (20) patient blankets stored on-top of upper cabinets above the sink/countertop, uncovered. 2. In the Clean Linen closet - stacked towels/wash cloths stored on shelves, uncovered; sharps containers and linen bags stored on the closet floor. 3. In the Computer Closet - urine specimen cups, exam gloves, and chux absorbent pads stored on the closet floor. 4. In the POC Lab/Sterile Reprocessing area - three (3) wrapped surgical procedure trays (clean) stored on the dirty side counter top. 5. In the POC Lab/Sterile Reprocessing area, the "Clean" and "Dirty" and "Sterile" areas/spaces were not labeled. 6. In Surgical Suite #1 and #2 - multiple sterilized/wrapped surgical procedure trays (5 in #1 and 3 in #2)stored on-top of the counter - uncovered/unprotected with other clean supply items. Interview during tour with facility staff revealed the blankets on-top of the cabinets were for patient	E 165	E165 The Facilities Coordinator re-trained the staff on meeting PPHS's high standards of safe and proper storage on 4/8/14. The following were addressed: 1. Blankets were immediately removed from the cabinet tops and stored in plastic bags. New resealable sanitary storage bags were ordered that will be utilized for the storage of blankets, towels, and washcloths. 2. Sharps containers and linen bags have been removed from the floor of the closet and stored on designated shelving. 3. All medical supplies are now stored in designated medical closets including urine cups, chux, and exam gloves. 4. Staff was immediately retrained on proper storage of wrapped surgical trays and on the management of clean areas. 5. TO ensure proper labeling of sterile supplies, labels and signs were made and hung indicating "sterile", "clean", and "dirty" areas. 6. Staff was immediately retrained on the proper storage of wrapped surgical trays.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 7 use during recovery. Interview confirmed the blankets were stored uncovered. Interview revealed the clean linen closest was used to store clean supplies as well as linen. Interview confirmed the stacked towels/wash cloths stored in the clean linen closet were uncovered and the sharps containers and linen bags were being stored on the floor of the closet. Interview revealed the computer closet was used to store clean patient care supplies. Interview confirmed the urine specimen cups, exam gloves, and chux absorbent pads were stored on the closet floor. Interview revealed the three (3) surgical procedure trays had been cleaned and wrapped. Interview revealed they were considered clean. Interview revealed the trays were awaiting sterilization in the autoclave. Interview confirmed the surgical procedure trays were being stored on the dirty side counter top. Interview revealed when surgical procedure trays have been sterilized and removed from the autoclave, they are stored in the Surgical Suites on the counter-tops. Interview confirmed the sterile surgical procedure trays were stored on the counter tops in Surgical Suite #1 and #2 - uncovered/unprotected during surgical procedures.	E 165	The proper storage of supplies and the proper use of "clean" and "dirty" areas will be monitored during bi-weekly visits by the new Regional Director and monthly during visits from the Facilities Coordinator.	
E 166	.0315 HOUSEKEEPING 10A-14E .0315 Abortion clinics shall meet the standards for sanitation as required by the Division of Environmental Health in the rules and regulations governing the sanitation of private hospitals, nursing and rest homes, sanitariums, sanatoriums, and educational and other institutions, 10 NCAC 10A, with special emphasis on the following:	E 166		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 166	Continued From page 8 (1) There must be cleaning of such a frequency as to maintain the floors, walls, woodwork and windows in a manner to minimize the spread of dust particles in the atmosphere. Accumulated waste material must be removed at least daily. (2) The premises must be kept free from rodents and insect infestation. (3) Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. (4) Linen which comes directly in contact with the patient shall be provided as needed for each individual patient. No such linen shall be interchangeable from one patient to another before being properly cleaned, sterilized, or laundered. This Rule is not met as evidenced by: Based on policy reviews, observations during tours and staff interviews the facility staff failed maintain a clean and sanitary environment. The findings include: Review of current facility policy "Infection Prevention Manual" reviewed October 2013/Implemented November 2013, revealed, pages 4-10 thru 4-12, "The patient care environment throughout the facility will be maintained in a state of cleanliness ... Environmental Surfaces ... Procedure: for cleaning exam rooms and laboratory at the end of a clinic day. ... Collect and remove waste ... Clean and disinfect exam lights ... Clean and disinfect all exterior surfaces of machines, equipment and tables ... and exam tables ... Clean and disinfect all horizontal surfaces ... Procedure: for	E 166		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 166	Continued From page 9 cleaning/disinfecting other patient care areas ... Check walls for visible soiling and clean if required ... Clean floors if not done by a contracted cleaning service ..." Observations during tour on 04/01/2014 at 1223 of the facility revealed the following: 1. In Surgical Suite #1 - the foot pedal covers of the surgical procedure table appeared soiled with dirt particles; there was excessive dust build up on the exterior surfaces of the ultrasound machine, counter top, base boards, and return air vent. Cob webs were noted spanned between the suction machine and floor exam lamp; Brownish/red (blood) dried residue was noted on the exterior power switch of the suction machine and on the floor adjacent to the foot of the surgical procedure table and red sharps container; a dead insect, black in color, was noted on the floor adjacent to the foot lamp. 2. In Surgical Suite #2 - there was excessive dust build up on the surfaces of the counter top, base boards, and return air vent. The trash receptacle was overflowing. 3. In the Staff breakroom - there was a dead insect, brown in color, in the sink. The trash receptacle was overflowing. 4. In the main lobby - the floors had excessive dust/dirt particles on the carpet. Interview with facility staff during tour revealed the contracted housekeeping staff only come on Wednesday and Saturday. Interview confirmed the above findings. Interview on 04/02/2014 at 0930 with Clinic Management Staff revealed the contracted housekeeping staff cleaning schedule is twice per	E 166	E166 In response to Housekeeping that fell well below standards, the entire facility's cleaning program was revamped. The janitorial company was immediately terminated and a new company has been retained that will provide professional cleaning prior to and after each surgical services day (currently surgical services are offered once per week). The health center staff members whose job duties have included daily facilities maintenance were immediately retrained by senior staff on daily duties for cleaning including waste removal, proper method for cleaning all surfaces, and general cleanliness that meets high standards for operations. Following the audit, PPHS immediately conducted a thorough "top to bottom" cleaning supervised by the Facilities Coordinator and the new janitorial service will conduct a second deep cleaning in mid-April. New janitorial supplies have been purchased, including the chemicals needed for cleaning as prescribed in the agency Infection Prevention Policy.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0020	A. BUILDING: _____ B. WING _____	04/02/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WILMINGTON	1925 TRADD COURT WILMINGTON, NC 28401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 166	Continued From page 10 week on Wednesday and Sunday. Interview revealed the facility is in the process of seeking a new cleaning company, because of issues identified with the current company not following the terms of their contract. Interview revealed the facility was last cleaned by the contracted cleaning service on March 30, 2014 (2 days prior to surveyor observations, the facility was closed on Monday, March 31, 2014).	E 166	The Office Park Association, which maintains the complex in which our office is located, is responsible for the extermination needs and maintains the exterminator contract. Nevertheless, PPHS insists on the highest standards and is prepared to independently manage extermination if building management shortfalls occur. The staff was trained on 4/8/14 regarding taking swift action if any insect or rodent issues arise, including immediate cleaning of any areas where a dead insect is found and immediately informing the Facilities Director. The new Regional Director and the Facilities Coordinator will be responsible for inspecting the facility for cleanliness during their bi-weekly and monthly visits.	

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 24, 2015

Kelly Brinn, Office Manager
Women's Health Alliance Chapel
120 Conner Dr Ste 101
Chapel Hill, NC 27515

Re: Recertification Survey

Dear Ms. Brinn,

Thank you and your staff for the assistance and cooperation extended during the Recertification survey at Women's Health Alliance Chapel in Chapel Hill, NC June 24, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortions. As a result of the survey, standard level deficiencies were identified with respect to .0304 Admission and Discharge and .0306 Personnel Records .

Enclosed please find STATE Form , "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies should be submitted and include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.

(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and

(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form CMS 2567, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

/Cecilia B. Boone/

Cecilia B. Boone, RN
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

Enclosures: CMS 2567 Statement of Deficiencies

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	06/24/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	.0304(D) ADMISSIONS AND DISCHARGE 10A-14E .0304 (d) Following admission and prior to obtaining the consent for surgery required by Rule .0305(a) of this Section, representatives of the clinic's management shall provide to each patient the following information: (1) A fee schedule and any extra charges routinely applied, (2) The name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included; (3) Instructions for post-procedure emergencies as outlined in Rule .0313(d) of this Section; (4) Grievance procedures a patient may follow if dissatisfied with the care and services rendered; and (5) The telephone number of the Complaints Investigation Branch of the Division. This Rule is not met as evidenced by: Based on closed medical record review and administrative staff interview the clinic staff prior to obtaining the consent for a Medical Abortion Procedure (MAB) failed to inform if the attending physician had hospital admitting privileges or in the absence of admitting privileges a statement to that effect in 1 of 1 MAB performed ((#1). The findings include: Medical record review of patient #1 revealed the patient had a MAB on /2015. Review of the record did not reveal any documentation the attending physician had hospital admitting	E 136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	06/24/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 136	Continued From page 1 privileges. Medical record review did not reveal documentation if the physician did not have admitting privileges. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed there was no documentation available prior to obtaining consent for the MAB, the attending physician had hospital admitting privileges. The interview revealed there was no available documentation he did not have hospital admitting privileges.	E 136		
E 147	.0306(B) PERSONNEL RECORDS 10A-14E .0306 (b) Job Descriptions: (1) The facility shall have a written description which describes the duties of every position. (2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required. (3) The facility shall review annually and update all job descriptions, and shall provide a current copy to each employee or contractual employee assigned to the position. This Rule is not met as evidenced by: Based on personnel file reviews and administrative staff interview the facility staff failed to review job descriptions annually, and update all job descriptions in 3 of 3 employee files reviewed (#1, #2,and #3). The findings include:	E 147		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	06/24/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 147	Continued From page 2 Review of 3 of 3 personnel files (employees #1, #2 and #3) revealed no documentation of annual review/update of the employees job description. Interview with the Clinic Manager on 06/24/2015 at 1505 revealed the job descriptions had not been reviewed or updated annually. The interview revealed the clinic was in the process of working with the North Carolina Quality Assurance and review of the job descriptions were not completed.	E 147		

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

April 11, 2014

Ms. De Stokes, RMM, CPC, Practice Manager
Women's Health Alliance
120 Conner Dr. Suite 101
Chapel Hill, NC 27515

Re: State Licensure Survey

Dear Ms. Stokes,

Thank you and your staff for the assistance and cooperation extended during the state licensure survey at Women's Health Alliance in Chapel Hill on April 3, 2014. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortions. As discussed at the exit conference, state licensure deficiencies were identified with respect to **10A NCAC 14E .0305 Medical Records; .0312 Medications & Anesthesia; and .0314 Cleaning of Materials and Equipment.**

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed State form 2567, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (252) 361-3361.

Sincerely,

Duane Jones, BSN, RN, EMT-P
Nurse Consultant
Acute and Home Care Licensure and Certification

Enclosures: State Form - Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered. This Rule is not met as evidenced by: Based on medical record review and staff interview, the clinic staff failed to have a witnessed voluntarily-signed informed consent for each surgery or procedure in 1 of 4 clinic records reviewed of patients that had abortion procedures (#3); and failed to verify the patient's full and true name for 4 of 4 patient's who had abortion procedures (#1, #2, #3, #4). The findings include: 1. Closed electronic medical record review for Patient #3 revealed a 32 year-old pregnant female who was 6 weeks 6 days gestation that had a surgical abortion procedure on '2013. Record review revealed no available documentation of an informed consent signed by	E 137	E137 Medical Records This rule will be met as evidenced by: Medical Record Review quarterly by the clinical supervisor. Benchmark - in 90 days the clinical supervisor will review 100% of the patient charts for medical and surgical abortions for 100% compliance. Monitoring will continue every 90 days until 100% compliance achieved. Initiated - 5/31/14 Medical record review will consist of of 100% chart review of all patients that have had medical or surgical abortions during the quarter. Review will check to make sure each patient's chart includes the date and time of admission and discharge; the full and true name of the patient; address, date of birth, nearest of kin; diagnosis, duration of pregnancy; condition on admission, and discharge attending physician; a witnessed voluntarily-signed consent for each procedure; a complete history and physical exam by a physician; allergies; The patients true and full name will be validated at check in by the administrative staff by requiring a photo ID. Effective 05/01/2014. ID will be scanned into the patient charts. The clinical staff assisting with the abortion will also validate the patients ~~true and full name by checking off~~	06/03/2014 05/31/2014

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 1 the patient for the surgical procedure performed on 06/13/2013. Interview with Clinic Management Staff on 04/03/2014 at 1500 revealed they were unable to locate the surgical procedure consent for Patient #3. Interview revealed the consent should have been scanned into the electronic medical record. 2. Closed electronic medical record review for Patient #1 revealed a 24 year-old pregnant female who was 6 weeks 6 days gestation that had a surgical abortion procedure on /2013. Record review revealed no available documentation of verification of the patient's full and true name. Interview with Clinic Management Staff on 04/03/2014 at 1500 revealed the clinic staff does not ask for a photo identification in order to verify the patient's full and true name. Interview revealed the clinic use to make copies of the patient's driver's license, but stopped due to the "Red Flag Rule." Interview revealed the clinic staff rely on the documentation provided by the patient. 3. Closed electronic medical record review for Patient #2 revealed a 48 year-old pregnant female who was 5 weeks gestation that had a medical abortion procedure on /2013. Record review revealed no available documentation of verification of the patient's full and true name. Interview with Clinic Management Staff on 04/03/2014 at 1500 revealed the clinic staff does not ask for a photo identification in order to verify the patient's full and true name. Interview revealed the clinic use to make copies of the patient's driver's license, but stopped due to the "Red Flag Rule." Interview revealed the clinic staff rely on the documentation provided by the patient.	E 137	a check list that certifies they looked at the patients photo ID, Name, DOB, and listed Date of admission, Start time,diagnosis, condition on admission,address, nearest of kin, physician, consent form signed, signature of physician, copy of History and physicial, Allergies, and any preexisting conditions Staff education will be completed by a staff meeting & staff will be given copies of the new guidlines and will sign signifying the understood the guidelines. Effective 5/31/14 The clinical supervisor will review with the staff the findings after each quarterly review to correct any deficiencies found. Clinical supervisor will sign off a check list each quarter attesting to the fact she reviewed the records.	05/31/2014

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULO BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 2 4. Closed electronic medical record review for Patient #3 revealed a 32 year-old pregnant female who was 7 weeks gestation that had a surgical abortion procedure on /2013. Record review revealed no available documentation of verification of the patient's full and true name. Interview with Clinic Management Staff on 04/03/2014 at 1500 revealed the clinic staff does not ask for a photo identification in order to verify the patient's full and true name. Interview revealed the clinic use to make copies of the patient's driver's license, but stopped due to the "Red Flag Rule." Interview revealed the clinic staff rely on the documentation provided by the patient. 5. Closed electronic medical record reviev for Patient #4 revealed a 26 year-old pregnant female who was 4-5 weeks gestation that had a medical abortion procedure on /2013. Record reviev revealed no available documentation of verification of the patient's full and true name. Interview with Clinic Management Staff on 04/03/2014 at 1500 revealed the clinic staff does not ask for a photo identification in order to verify the patient's full and true name. Interview revealed the clinic use to make copies of the patient's driver's license, but stopped due to the "Red Flag Rule." Interview revealed the clinic staff rely on the documentation provided by the patient.	E 137	Medical Records E-141 Each log will list the following: patent name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, name of assistant, date and time of the procedure, any complications. Effective 04/30/14 Clinical Supervisor will monitor logs quarterly for 100% compliance. Effective 05/31/2014 Clinical Supervisor will check off that she's monitored the abortion logs quarterly. Effective 05/31/2014 The Clinical Supervisor will educate staff of the administrative plan to monitor procedure logs during monthly staff meeting. Effective 05/06/2014 Medical Records E141 A separate Log for medical and surgical abortions will be maintained in the abortion clinic notebook. 05/31/2014y	05/31/2014
E 141	.0305(E) MEDICAL RECORDS 10A-14E .0305 (e) The facility shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least	E 141	The log will list:	05/31/2014

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 141	Continued From page 3 patient name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, and date and time of procedure. This Rule is not met as evidenced by: Based on clinic log reviews and staff interviews the clinic staff failed to maintain a daily procedure log containing the type of procedure, time of procedure, and Name of the Registered Nurse (RN) on duty. The findings include: Review on 04/03/2014 of the clinic daily procedure log from 01/01/2013 to 04/03/2014 revealed no documentation of the time of procedure on log entries. Further review revealed on the following date(s) log entries, the name of the RN on duty was not documented: 01/24/2013; 06/13/2013; and 09/12/2013. Further review revealed on the following date(s) log entries, the type of procedure performed was not documented: 02/16/2013 and 09/12/2013. Interview on 04/03/2014 with Clinic Management Staff confirmed the log did not contain the time of procedure and that there were incomplete documentation of the type of procedure, and name of RN on duty for the aforementioned log entries.	E 141	patient name, estimated length of gestation, type of procedure, name of physician, name of registered nurse on duty, name of assistant, date and time of the procedure. & any complications. Clinical supervisor will monitor the logs 05/31/2014 quarterly to make sure that 100% of the quidelines are followed. Effective 05/31/2014 Clinical supervisor will have a check sheet to check off the date that the log was monitored Effective 05/31/2014 The clinical supervisor will educate the staff regarding the changes and updates to the medical and surgical patient log for abortions that will be kept in the abortion notebook in the clinical supervisors office. This will be done at a staff meeting 05/06/2014 Benchmark - clinical supervisor will audit 100& of medical and surgical charts in 90 days for 100% compliance. Once 100% in compliance with use of logs Clinical supervisor may utilize random sampling of all the medical and surgical abortions. done in a quarter for review. ie: if 5 abortions done clinical supervisor may review 2 of the 5 patient charts to ensure 100% compliance is maintained.	05/31/2014
E 159	.0312(A) MEDICATIONS AND ANESTHESIA 10A-14E .0312 (a) Medication (1) No medication or treatment shall be given except on written order of a physician. (2) Medications must be administered	E 159	Medication E 159 A new medication protocol was implemented by the physicians. Chapel Hill OB/GYN Abortion Clinic protocol states that only licensed personnel (RN or Physician) may	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 159	Continued From page 4 in accordance with the Nurse Practice Act of the State of North Carolina, and must be recorded in the patient's permanent record. This Rule is not met as evidenced by: Based on closed record reviews, personnel file review, and staff interviews, the clinic failed to ensure medications were administered by a Registered Nurse (RN) or Licensed Practical Nurse (LPN) in accordance with the Nurse Practice Act of the State of North Carolina for 2 of 2 patients who were administered medications and had a surgical abortion procedure performed (#1, #3). The findings include: 1. Closed electronic medical record review on 04/03/2014 for Patient #1, revealed a 24 year old pregnant female who presented to the facility on /2013. Record review revealed "History of Present Illness" as "Patient Words: Menstrual Extraction (ME)." Review revealed "Assessment & Plan" as "Unwanted Pregnancy (V61.7)." Review revealed "Procedure" as "Induced Abortion, By Dilatation and Curettage (59840)." Record review revealed "Per VC (physician's initials) administered Ketorolac (Non-Steroidal Anti-Inflammatory Drug for analgesia) 60 milligrams (mg)/2 milliliters (ml) to patient RUOQ (Right Upper Outer Quadrant). Pt (patient) tolerated injection well. ... Phenergan (Phenothiazine derivative for nausea) 25 mg/ml, administered 1 ml to pt. LUOQ (Left Upper Outer Quadrant). ... (name of CMA #1) CMA (Certified Medical Assistant)/AAMA (American Association of Medical Assistants)."	E 159	administer medication before, during or after an abortion procedure. Staff education was done by a staff meeting where the new policies and procedures were reviewed regarding abortion procedures in the clinic. Effective 05/06/2014 A sign in sheet was provided during clinical the meeting for staff to attest they understood the new policy and procedure. Effective 05/06/2014 Quarterly review of 100 % of the medical and surgical abortion charts by the clinical supervisor will make sure that this policy is followed. Once 100 % compliance is obtained then the clinical supervisor may start to do random chart reviews of medical and surgical abortions quarterly.	05/31/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 159	Continued From page 5 Personnel File review on 04/03/2014 for CMA #1 revealed, a job description signed and dated 05/03/2007. Review revealed "I. Title: Staff Nurse/Certified Medical Assistant ... V. General Summary of Duties: Performs duties as allowed by North Carolina Scope of Practice for the degree/license currently held by this employee. ..." Review revealed documentation of a CMA certification from the AAMA dated April 1, 2008. Further review revealed no available documentation of a license to practice as a RN or LPN in the State of North Carolina. Interview on 04/03/2014 at 1500 with Clinic Management Staff revealed a Menstrual Extraction is a surgical abortion. Further interview revealed CMA #1 is a Certified Medical Assistant. Interview revealed CMA #1 was not a RN or LPN. Interview revealed CMA #1 was the only CMA who assisted with surgical abortion procedures. Interview revealed it was routine for CMA #1 to administer medications to patients per the physician's order for procedures. Interview revealed CMA #1 is unavailable for interview. Interview confirmed the documentation in Patient #1's medical record, that CMA #1 administered Ketolorac and Phenergan to the patient on 09/12/2013. Interview confirmed the patient was not administered the medications by a RN or LPN. 2. Closed electronic medical record review on 04/03/2014 for Patient #3, revealed a 32 year old pregnant female presented to the facility on /2013. Record review revealed "History of Present Illness" as "Patient Words: Patient Presents for ME." Review revealed "Assessment & Plan" as "Unwanted Pregnancy (V61.7)." Review revealed "Procedure" as "Induced Abortion: Abortion (59840)." Record review	E 159	see above see above	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 159	Continued From page 6 revealed "Per VC (physician's initials) administered Toradol (Non-Steroidal Anti-Inflammatory Drug for analgesia) 60 mg/2 ml to patient LUOQ (Left Upper Outer Quadrant). Patient tolerated injection well. ... Also administered Demerol (Schedule II, Controlled Substance, Opioid Analgesic for pain) 50 mg with Promethazine (Phenothiazine derivative for nausea) 12.5 mg to patient RUOQ (Right Upper Outer Quadrant). ... (name of CMA #1) CMA/AAMA." Personnel File review on 04/03/2014 for CMA #1 revealed, a job description signed and dated 05/03/2007. Review revealed "I. Title: Staff Nurse/Certified Medical Assistant ... V. General Summary of Duties: Performs duties as allowed by North Carolina Scope of Practice for the degree/license currently held by this employee. ..." Review revealed documentation of a CMA certification from the AAMA dated April 1, 2008. Further review revealed no available documentation of a license to practice as a RN or LPN in the State of North Carolina. Interview on 04/03/2014 at 1500 with Clinic Management Staff revealed a Menstrual Extraction is a surgical abortion. Further interview revealed CMA #1 is a Certified Medical Assistant. Interview revealed CMA #1 was not a RN or LPN. Interview revealed CMA #1 was the only CMA who assisted with surgical abortion procedures. Interview revealed it was routine for CMA #1 to administer medications to patients per the physician's order for procedures. Interview revealed CMA #1 is unavailable for interview. Interview confirmed the documentation in Patient #3's medical record, that CMA #1 administered Toradol, Demerol, and Promethazine to the	E 159	see above	

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 159	Continued From page 7 patient on 06/13/2013. Interview confirmed the patient was not administered the medications by a RN or LPN.	E 159		
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on review of facility policy, observations during tour, review of autoclave logs and staff interview, the clinic failed to ensure sterile instruments were not outdated and failed to ensure autoclave testing was performed per clinic policy. The findings include: 1. Review of the clinic's policy, "Infection Control Policy", dated 2013, revealed, "...3. Storage of Supplies ...c. Supplies must be within expiration date. i. Sterile items must be clean, within date...". Observation during tour of the clinic on 04/03/2014 at 1145 revealed a drawer at the nurses' station containing sterile instruments wrapped in clear packs. Observation revealed the following out of date supplies:	E 165	Cleaning of Materials and Equipment E - 165 Infection Control Policy dated 2013 was updated and signed by managing physician and effective -04/16/2014 Staff education: Staff meeting and review of the Infection Control Policy. Implementation of check list for sterile supplies and biological testing completed 05/31/2014 A clinical staff will be assigned to check sterile supplies, they must sign attesting this was done and that 100% of the sterile supplies in the clinic are in date for patient use. Effective 05/31/2014 The clinical supervisor will check the sterile supply cabinet monthly to verify 100% compliance for the next 90days.	05/31/2014 07/03/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 8 #1- expired 12/17/2013 (3 months, 14 days ago) #2 -expired 11/08/2013 (4 months, 26 days ago) #3- expired 12/17/2013 (3 months, 14 days ago) #4 - expired 10/22/2013 (5 months, 12 days ago) #5- expired 08/21/2013 (7 months, 13 days ago) #6- expired 04/01/2014 (2 days ago) #7- expired 03/26/2014 (7 days ago) #8- expired 11/08/2013 (4 months, 26 days ago) #9- expired 06/27/2013 (9 months, 7 days ago) #10- expired 11/08/2013 (4 months, 26 days ago) #11- expired 08/21/2013 (7 months, 13 days ago) #12- expired 11/08/2013 (4 months, 26 days ago) #13- expired 11/08/2013 (4 months, 26 days ago) #14- expired 03/03/2014 (1 month ago) Interview on 04/03/2014 with a staff registered nurse revealed the sterile instrument packs are supposed to be checked monthly for out of date items. Interview confirmed there were 14 packs that were out of date. Interview on 04/03/2014 at 1500 with administrative staff confirmed the staff did not follow the clinic's infection control policy for ensuring sterile items were not out of date/expired. 2. Review of the clinic's policy, "Infection Control Policy", dated 2013, revealed, "...12. Sterilization a. Autoclaves: chemical and biological indicators must be used appropriately...III. Biological indicators are to be run weekly with results documented in the log book...". Review of the clinic's Biological Monitoring Log revealed a spore test was performed 12/19/2013, 01/20/2014 (1 month later), 02/18/2014 (1 month later), 03/05/2014 and 03/12/2014. Review	E 165	The check list will be in the Safety Data Book at the nursing station. Effective 05/31/2014 Weekly a second clinical staff member will be required to check the entire Safety Data book to make sure all clinical staff assigned to check the refrigerator, office temps, auto-clave sterilization, eyewash station, and medications, are signing and attesting that the checks are complete. 05/31/2014 Each month the clinical supervisor will check the data book to ensure that 100% of check lists are signed and up to date and the staff is in 100% compliance with the office safety policies. This will be done for the next 90 days to ensure 100% compliance and then will continue to be checked quarterly to maintain 100% compliance from staff. 2. The Autoclave Sterilization policy was reviewed and the staff re-educated about the importance of this assigned task. Biological Spore testing is to be done weekly and the monitoring log signed and dated each week. Clinical staff will be assigned to complete this task and be required to keep the biological book up to date. A second clinical staff will assigned to check this book weekly on Fridays for compliance.	06/03/2014 05/31/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0027	A. BUILDING: _____ B. WING _____	04/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH ALLIANCE CHAPEL	120 CONNER DR STE 101 CHAPEL HILL, NC 27515

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 165	Continued From page 9 revealed the last biological spore test was performed 03/12/2014 (3 weeks, 1 day). Interview on 04/03/2014 at 1515 with Clinic Management Staff revealed the biological testing should be done every two weeks. Interview revealed, "we need to change our policy because I didn't know it said weekly". Interview confirmed the staff failed to follow the clinic's policy for biological testing of the autoclave.	E 165	Clinical supervisor to check the biological testing book weekly for 100% compliance on testing for 90 days. Once compliance is meet, clinical supervisor may check book monthly for 100% compliance. Effective 05/31/2014 Staff Education: clinical supervisor will review the procedure for biological testing with all clinical staff members during staff meeting 05/06/2014.	06/03/2014 05/31/2014

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

June 17, 2015

Kelly Smith, Administrator
Planned Parenthood
4551 Yadkin Road
Fayetteville, NC 28303

Re: State Licensure Survey

Dear Ms. Smith:

Thank you and your staff for the assistance and cooperation extended during the state licensure survey at Planned Parenthood in Fayetteville, NC from June 9, 2015. The survey was conducted in order to determine the facility's compliance with the North Carolina Rules for Licensing Abortion Clinic. As discussed at the exit conference, state licensure deficiencies were identified with respect to 10A NCAC 14E .0313 Post-Operative Care.

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies may be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed form CMS 2567, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

Lynn Ethridge, RN, BSN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Enclosures: State Form - Statement of Deficiencies

Acute and Home Care Licensure and Certification Section
http://www.ncdhhs.gov/dhsr/
Phone: (919) 855-4620 ■ Fax: (919) 715-3073
Mailing Address: 2712 Mail Service Center • Raleigh, North Carolina 27699-2712
Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603

7/23/2015

JUL 01 2015

PRINTED: 06/15/2015
FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	080052	A. BUILDING: _____ B. WING _____	06/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD	4551 YADKIN ROAD FAYETTEVILLE, NC 28303

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	.0313(A) POST-OPERATIVE CARE 10A-14E .0313 (a) Patients whose pregnancy is terminated on an ambulatory basis should be observed in the abortion clinic for a reasonable number of hours, not less than one, to insure that no immediate post-operative complications are present. Thereafter, such patients may be discharged if their course has been uneventful. This Rule is not met as evidenced by: Based on policy review, review of medical records and staff interview, the facility failed to ensure a minimum of one hour observation after a procedure for 4 of 10 patient records reviewed (#5, #9, #4 and #6). Review of the facility's policies revealed no policy for observing a patient for a minimum of one hour after the procedure. 1. Closed medical record review of Patient #5 revealed a 37 year-old female who had a surgical abortion on /2015. Record review revealed Patient #15 was admitted to the recovery area at 1500 and was discharged a 1535 (35 minutes later). Record review revealed no documentation that Patient #5 signed out Against Medical Advice (AMA). Interview on 06/09/2015 at 1220 with administrative staff revealed the facility policy is to follow all State laws, including the requirement to observe patients for one hour after the procedure. Interview revealed, "if patients refuse to wait, they are asked to sign an AMA form". Interview confirmed Patient #5 was observed for 35 minutes and did not sign an AMA form.	E 161	10A-14E .0313 PPSAT is committed to the health and safety of our patients. PPSAT current policy is to follow all Federal and State regulations related to Abortion care. A copy of the North Carolina DFS AB requirements will be kept on-site as of July 18th, 2015 for staff reference. If a patient chooses to leave the health center prior to one hour, she will sign the Against Medical Advice (AMA) form with the specific language "I understand that leaving before the required one hour post-procedure recovery time could delay treatment of complications". This form will be implemented by July 18, 2015. The Health Center Manager will review with current nursing staff this requirement and the importance of documenting the time of discharge. The Health Center Manager will ensure nursing staff are trained in appropriate documentation of this requirement and notation of discharge time on July18, 2015. The Health Center Manager will conduct a weekly audit of a sample of charts to ensure compliance, specifically auditing charts of the RN staff member whose charts were cited in the report. The audit will continue until compliance is demonstrated.	7.18.15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	080052	A. BUILDING: _____ B. WING _____	06/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD	4551 YADKIN ROAD FAYETTEVILLE, NC 28303

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 1 2. Closed medical record review of Patient #9 revealed a 34 year-old female who had a surgical abortion on 2015. Record review revealed Patient #9 was admitted to the recovery area at 1405 and was discharged at 1440 (35 minutes later). Record review revealed no documentation that Patient #9 signed out Against Medical Advice (AMA). Interview on 06/09/2015 at 1220 with administrative staff revealed the facility policy is to follow all State laws, including the requirement to observe patients for one hour after the procedure. Interview revealed, "if patients refuse to wait, they are asked to sign an AMA form". Interview confirmed Patient #9 was observed for 35 minutes and did not sign an AMA form. 3. Closed medical record review of Patient #4 revealed a 28 year-old female who had a surgical abortion on /2015. Record review revealed Patient #4 was admitted to the recovery area at 1203 and was discharged at 1240 (37 minutes later). Record review revealed no documentation that Patient #4 signed out Against Medical Advice (AMA). Interview on 06/09/2015 at 1220 with administrative staff revealed the facility policy is to follow all State laws, including the requirement to observe patients for one hour after the procedure. Interview revealed, "if patients refuse to wait, they are asked to sign an AMA form". Interview confirmed Patient #4 was observed for 37 minutes and did not sign an AMA form. 4. Closed medical record review of Patient #6 revealed a 23 year-old female who had a surgical abortion on I/2015. Record review revealed	E 161	The PPSAT Director of Nursing has updated the Recovery Room Skills Checklist to reflect all requirements of providing Abortion care in NC, including the AMA patient signature if departing in less than one hour and the importance of documentation. When new nurses are on-boarded and trained, this tool will be used to ensure understanding of all requirements. A copy is attached.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROV /SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUC.	(X3) DATE SURVEY COMPLETED
	080052	A. BUILDING: _____ B. WING _____	06/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD	4551 YADKIN ROAD FAYETTEVILLE, NC 28303

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 161	Continued From page 2 Patient #9 was admitted to the recovery area at 1210. Review revealed no documented time of discharge. Interview on 06/09/2015 at 1220 with administrative staff revealed the facility policy is to follow all State laws, including the requirement to observe patients for one hour after the procedure. Interview revealed, "if patients refuse to wait, they are asked to sign an AMA form". Interview confirmed there was no documented time of discharge for Patient #6.	E 161		

Planned Parenthood®
Care. No matter what.
Planned Parenthood South Atlantic

☐ Asheville ☐ Blacksburg ☐ Chapel Hill ☐ Charleston ☐ Charlotte
☐ Charlottesville ☐ Columbia ☐ Durham ☐ Fayetteville ☐ Greensboro
☐ Raleigh ☐ Roanoke ☐ Vienna ☐ Wilmington ☐ Winston-Salem

Skills checklist: Recovery Room RN

Skill/Procedure	DP	NI	Observed by:	Date
Ensures that Narcotics being dispensed during clinic are counted at the beginning and end of each clinic and cosigned by another licensed staff or HCM. Notifies supervisor immediately if any discrepancies				
Prepares pre op medications to be dispensed				
Reviews patient's medical history for any contraindications				
Confirms patient identity prior to dispensing medication				
Dispenses medications with proper instructions				
Documents medication correctly and completely in patient record				
Signs out medication in appropriate QM Log				
Completes patient's ASA Physical Status Classification Score and documents appropriately				
Admits patient to Recovery Area				
Assesses VS every 15 minutes, including BP, HR, P, RR, LOC, pain or additional per MD order				
Offers patient comfort measures (heating pad, blanket, snack, etc.)				
Answers/clarifies any questions that patient may have concerning BCM, instructions etc.				
Assesses sedated patient for discharge with support person				
Assesses patient for bleeding and pain				
Provides aftercare instructions and ensures patient understanding				
Responds to emergencies quickly and effectively				
Participates and understands role in Emergency Drills				
Knows where to locate Emergency Cart, Emergency equipment, Oxygen, and Medications and knows their indications for use				
Has proficient IV skills				
Follows "high alert" Algorithm correctly if indicated				
Ensures that NC pts sign AMA if leaving prior to 1 hour in RR				
Conscious sedation – see separate checklist if applicable				
Follows all PPFA, PPSAT, HIPAA, OSHA guidelines				
Appropriately documents all assessments and findings				
Performs other duties as assigned by supervisor				

DP = Demonstrates Proficiency
NI = Needs Improvement

RN/LPN Signature_____ Date_____

Trainer's Signature_____ Date_____

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

May 15, 2015

Sharilyn Garcia, Health Center Manager
Planned Parenthood Of Winston Salem
3000 Maplewood Ave Ste 112
Winston-Salem, NC 27103

Re: State Licensure Recertification Survey

Dear Ms. Garcia,

Thank you and your staff for the assistance and cooperation extended during the state licensure survey at Planned Parenthood Of Winston Salem in Winston-Salem, NC from May 6, 2015 through May 7, 2015. The survey was conducted in order to determine the Clinic's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortions. As discussed at the exit conference, a deficiency was identified with respect to the surgical abortion procedure consent with the signature of the physician performing the surgical abortion procedure .

Enclosed please find State Form, "Statement of Deficiencies and Plan of Correction," containing the cited deficiency. A plan of correction for the deficiency must be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
(c) The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 60 days from the date of the survey and should be indicated in the right-hand column).

An ***original*** of the enclosed STATE form, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

Cecilia B. Boone, RN
Nurse Consultant, Lead
Acute and Home Care Licensure and Certification Section

Acute and Home Care Licensure and Certification Section
http://www.ncdhhs.gov/dhsr/
Phone: (919) 855-4620 ■ Fax: (919) 715-3073
Mailing Address: 2712 Mail Service Center • Raleigh, North Carolina 27699-2712
Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0009	A. BUILDING: _____ B. WING _____	05/07/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WINSTON SALEM	3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103

6/19/2015-CBB
6/23/2015 TB

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered. This Rule is not met as evidenced by: Based on policy and procedure review, closed medical record reviews and staff interviews, the clinic staff failed to maintain a complete medical record; by failing to ensure the physician performing surgery signed a witnessed, voluntarily-signed consent in 8 of 8 medical records reviewed of patients having a surgical abortion procedure (SAB) completed (#'s 7, 4, 5, 1, 8, 3, 10, 9). The findings included: Review of the clinic's policy titled "Surgical Abortion Policy, V11-A-1", revised June 2012, revealed when a patient has a SAB there must be a "Witnessed voluntarily-signed consent for each surgery or procedure and signature of the	E 137	At Planned Parenthood South Atlantic (PPSAT), patient signatures on consents for surgical and medication abortions require a witness by trained staff members. Prior to and after each procedure, physicians review and sign off on the patient's medical record to ensure histories are reviewed, required examinations are performed, voluntary consents are obtained, and patients are witnessed as per NCDHHS regulations 10A-14E.0305(a). Inspectors clarified that in addition to patient and witness signatures, NCDHHS regulation 10A-14E.0305(a) also requires physician signature on consents. PPSAT Plan of Correction: 1. For paper medical records (downtime forms) we have revised the signature line of the consents CIIC-022 and CIIC-027 to include physician signature directly on the consent (please see attached). This went into effect 5/11/15. 2. For electronic records, we have created a system by which the physician may directly sign the consents (CIIC-022 and CIIC-027), in addition to the medical chart as a whole. The physician's signature will be present on printed copies of these consent forms. Training in the process is planned for 06/04/15 and full implementation will take place by 06/08/15. 3. Administrative staff will review all charts at the end of each clinic day to ensure compliance with physician signatures on CIIC-022 and CIIC-027 forms. Daily monitoring will continue until consistent compliance is demonstrated. 4. Review for compliance with physician signature on CIIC-022 and CIIC-027 will be added to annual surgical and medical abortion chart audits scheduled for July 2015.	5/11/15 06/08/15 Daily July 2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0009	A. BUILOING: _____ B. WING _____	05/07/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WINSTON SALEI	3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 1 physician performing the procedure"; Further review of the policy revealed under "Medical Record Documentation XI" the medical record must contain a "Witnessed, voluntarily-signed consent for each surgery or or procedure and signature of the physician performing the procedure". 1. Medical record review of patient #7 revealed the patient had a SAB completed on /2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 2. Medical record review of patient #4 revealed the patient had a SAB completed on /2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 3. Medical record review of patient #5 revealed the patient had a SAB completed on /2015. Medical record review revealed no documentation of the signature of physician performing the SAB	E 137		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0009	A. BUILDING: _____ B. WING _____	05/07/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WINSTON SALEM	3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 2 on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 4. Medical record review of patient #1 revealed the patient had a SAB completed on /2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 5. Medical record review of patient #8 revealed the patient had a SAB completed on /2015. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 6. Medical record review of patient #3 revealed the patient had a SAB completed on 2014.	E 137		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0009	A. BUILDING: _____ B. WING _____	05/07/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WINSTON SALEI	3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 3 Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 7. Medical record review of patient #10 revealed the patient had a SAB completed on /2014. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed. 8. Medical record review of patient #9 revealed the patient had a SAB completed on /2014. Medical record review revealed no documentation of the signature of physician performing the SAB on the witnessed, voluntarily-signed consent. Interview on 05/06/2015 at 1800 with the Health Center Manager revealed the physician did not sign the witnessed, voluntarily-signed consent. The interview revealed there was no documentation available of a consent signed by the physician performing the SAB. The interview revealed the Clinic policy was not followed.	E 137		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0009	A. BUILDING: _____ B. WING _____	05/07/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WINSTON SALEI	3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 137	Continued From page 4	E 137		

Planned Parenthood®
Care. No matter what.
Planned Parenthood South Atlantic

☐ Asheville ☐ Blacksburg ☐ Chapel Hill ☐ Charleston ☐ Charlotte
☐ Charlottesville ☐ Columbia ☐ Durham ☐ Fayetteville ☐ Greensboro
☐ Raleigh ☐ Roanoke ☐ Vienna ☐ Wilmington ☐ Winston-Salem

What is an in-clinic abortion?
There are two kinds of in-clinic abortions

- **In-clinic suction abortion:** suction is used to take the pregnancy out of your uterus (womb).
- **In-clinic D&E abortion:** both suction and surgical tools are used to take the pregnancy out of your uterus (womb).

Which procedure you have and the way the abortion is done depends on how long you've been pregnant. This is figured out by counting from the first day of your last period or by an ultrasound.

At Planned Parenthood South Atlantic, we offer both kinds of in-clinic abortion.

Before having an abortion, you need to know the most common benefits, risks, side effects, emotional reactions, and other choices you have. We are happy to answer any questions you have.

What are the benefits of abortion?
- It is a safe and effective way to end a pregnancy.

What are the side effects of abortion?
Side effects don't usually last long and don't need to be treated. Call us if the problem doesn't go away or you are worried. Common side effects are
- light or medium bleeding. If your bleeding is very heavy — soaking more than 2 maxi pads for 2 hours in a row, call us.
- cramping
- feeling tired (usually from anesthesia and/or pain medications)

Besides an in-clinic abortion, what other choices do I have?
If you are pregnant, you have three options to think about — abortion, adoption, and parenting.

If you choose abortion and are less than 9 weeks pregnant, you may be able to use the abortion pill. You can also have an abortion in a hospital or by another doctor or nurse, now or later in your pregnancy. But, there are more risks the longer you wait to have an abortion.

We can talk about any of these options with you, and help you with whatever you decide to do.

What are the risks of abortion?
Abortion is very safe. But, there are risks with any medical procedure. Your risk may be higher if you
- are not healthy
- have had a c-section or certain other surgeries

Risk also goes up the longer you are pregnant and if sedation is used.

Risks linked with in-clinic abortion are
- **Incomplete abortion** — This means some of the pregnancy tissue may be left inside the uterus (womb). This may

What are the risks of abortion? (con't)

lead to heavy bleeding, infection, or both. If this happens, a procedure may need to be done again. Other tests or treatments may be needed.

- **Blood clots in the uterus** — Clots may cause cramping and belly pain. A procedure may need to be done again.
- **Infection of the uterus** — Most infections can be found and treated with medicines. But, there is a small chance that a suction procedure may need to be done again. You may have to go to the hospital, or even have surgery to treat the infection.
- **The pregnancy doesn't end** — Sometimes the abortion does not end the pregnancy. It may be because the pregnancy was not in the uterus or for some other reason. If the pregnancy is ectopic (not in the uterus), you will need to see a doctor or nurse who can treat it or go to the emergency room right away. Some women may need medicine and others may need surgery. If the pregnancy is still in the uterus, a procedure may need to be done.
- **Heavy bleeding (hemorrhage)** — This may require treatment with medicine, a repeat procedure, blood transfusion, and/or surgery — including possible hysterectomy (removal of the uterus).
- **Injury to the cervix (opening to the uterus)** — This may be treated with medicine or rarely with stitches
- **Injury to the uterus or other organs** — A surgical tool may go through the wall of the uterus, which could damage organs inside the body like the intestines, bladder, or blood vessels. Treatment may mean just watching and waiting for a while or surgery on your belly. There is a small chance that hysterectomy (removal of the uterus) may be needed. Scars may develop inside the uterus, which may need to be treated.
- **Allergic and/or drug reaction** — Some women may be allergic to the local anesthetic (numbing medicine) or to other medicines used. It is important that you tell us about all medicines you are allergic to. Also, tell us about any medicines you are taking. We need to be sure they are safe to mix with medicines we give you.
- **Death** — Death from an abortion procedure is very rare. The risk of death from an abortion goes up the longer you are pregnant.
  - When an abortion is done when a woman is less than 20 weeks pregnant (about 4 ½ months), the risk of death from a full-term pregnancy or childbirth is higher than the risk of abortion. After 20 weeks of pregnancy, the risks are about the same.

What will be done to get me ready for the abortion?

Education and Consent — A staff person will

- talk to you about your medical history
- tell you about the abortion
- answer any questions you have
- get your written consent (permission) to have the abortion

Laboratory Tests — You will have

- a pregnancy test (if an ultrasound doesn't show a pregnancy in the uterus)
- a blood test to check your Rh factor - a protein on the outside of red blood cells
- a blood test to see if you have anemia (low iron)
- other tests your doctor or nurse thinks you need

Ultrasound — You may need an ultrasound. It can help tell how long you've been pregnant. A probe (like a wand) will be placed on your abdomen (belly) or into your vagina to get a picture of the pregnancy.

Physical Exam — You will have your blood pressure taken and have a pelvic exam. You may get other exams if the doctor or nurse thinks you need them.

Review — A doctor or nurse will talk to you about your medical history, exams, and any tests you had to decide if the abortion can be done at Planned Parenthood.

Pain Medicine — A staff person will tell you about pain medicines that can be used. You will be given written instructions to read and sign if you are going to get medicine to make you relaxed or drowsy during the abortion.

Opening (dilating) your cervix — Your cervix may need to be opened (dilated) before your abortion. If so, you will be given separate information about the medicine and/or steps that will be taken to open (dilate) your cervix.

What will happen to me during my abortion?

You will be given pain medicine. You may get medicine to numb your cervix. You and your doctor will talk about what other medicines you may need to help with pain and discomfort during your abortion.

After your pain medicine begins to work, your doctor will decide if your cervix is ready (open enough). If your cervix needs to be dilated (opened) more, your doctor will stretch it with dilators.

When your cervix is stretched open enough, the contents of your uterus (womb) are taken out with suction. Suction is used by putting a small plastic tube into your uterus and connecting it to a hand-held or electric suction machine. Surgical tools may be put into the uterus through the opening in the cervix. The way it is done will depend on how long you've been pregnant.

You may feel cramping during and after the abortion as your uterus gets smaller. Your doctor may also use a curette (a thin surgical tool) to remove the pregnancy. What has been removed will be looked at to help make sure the abortion is finished.

What will happen to me after my abortion?

You will be taken to a recovery area for rest. We will also watch to see if you are OK. You will be given instructions on what to expect and how to care for yourself. We will talk about birth control plans with you, unless this was already done.

When you feel comfortable, in about 30 minutes or so, you may leave. You may need someone to drive you home. This depends on if you had medicine to make you relaxed or drowsy during the abortion.

What else do I need to know?
You will be given instructions on caring for yourself after your abortion and information on when to come back to us if you are having a problem.

No promise can be made about the outcome of your abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at the health center. We are happy to help you.

☐ I am having an in-clinic suction abortion

☐ I am having an in-clinic D&E abortion

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

☐ CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

Signature of any other person consenting _____ Date _____

Relationship to client _____

I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

Witness Signature _____ Date: _____

Physician signature _____ Date _____

Health Center Contact Info		
ASHEVILLE 828-252-7928	**BLACKSBURG** 540-951-7009	**CHAPEL HILL** 866-942-7762
CHARLESTON 843-628-4380	**CHARLOTTE** 704-536-7233	**CHARLOTTESVILLE** 434-296-1000
COLUMBIA 803-256-4908	**DURHAM** 866-942-7762	**FAYETTEVILLE** 866-942-7762
GREENSBORO 336-373-0678	**RALEIGH** 919-833-7534	**ROANOKE** 540-562-3457
VIENNA 304-295-3331	**WILMINGTON** 910-762-5566	**WINSTON-SALEM** 336-768-2980

Planned Parenthood®
Care. No matter what.
Planned Parenthood South Atlantic

☐ Asheville ☐ Blacksburg ☐ Chapel Hill ☐ Charleston ☐ Charlotte
☐ Charlottesville ☐ Columbia ☐ Durham ☐ Fayetteville ☐ Greensboro
☐ Raleigh ☐ Roanoke ☐ Vienna ☐ Wilmington ☐ Winston-Salem

What is the abortion pill and how do I take it?
"Abortion pill" is a popular name for a medicine called mifepristone. It is the first pill you will take to end your pregnancy and starts the abortion process. Pregnancy needs a hormone called progesterone to grow normally. Mifepristone blocks the body's own progesterone, causing the pregnancy to end.

After you take the abortion pill, you need to take a second medicine called misoprostol. It opens the cervix and makes the uterus contract. This empties the uterus and completes the process. The whole process is called medication abortion.

There are a few different ways to take these medicines. There is the way approved by the FDA. Other ways to take the medicines have been studied. You might take a different amount of medicine. When you take the medicine might be different. These other ways are also safe and are usually more effective than the FDA way. We will give you instructions how to take your pills. It is important to follow these instructions.

After you take the abortion pill and misoprostol, you must make sure the medicines worked and that you're no longer pregnant. This will be done by having an ultrasound at the clinic in 10-14 days.

Before you have an abortion, you need to know the most common benefits, risks, side effects, emotional reactions, and other choices you have. We are happy to answer any questions you have.

What are the benefits of the abortion pill?
Using the abortion pill together with misoprostol is safe and effective. At Planned Parenthood, it works about 98 out of 100 times. Women can use it in the first 9 weeks (63 days) of pregnancy.

What are the side effects of the abortion pill?
Side effects usually do not last long. They usually need little or no treatment.

- **Cramping is expected** — It will be the worst after you take the misoprostol. Milder cramps may last a day or 2 after that.
- **Bleeding is expected** — It will be heaviest soon after taking the misoprostol. You may bleed or spot for 4 to 6 weeks after the abortion.
- **Fever** — Having a temperature of 99-100°F is okay. It should only last a short time.
- **Other** — It is common to have diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. They usually lighten up 3 days later. They usually stop within 2 weeks.

Can I breastfeed if I take the abortion pill?
Both misprostol and mifepristone can pass into your breast milk in small amounts after you take it. These amounts shouldn't cause any problems for you or your baby. Tell your doctor or nurse if you're breastfeeding so you can work out the best plan together.

What feelings do women have after abortion?
Having a wide range of feelings is normal. Most women feel relieved and do not regret their decision. Others may feel sad, guilty, or regret after an abortion, just as they may after having a baby. If your mood keeps you from doing the things you usually do each day, call us. We can help or send you to someone who can.

Besides taking the abortion pill, what other choices do I have?
If you are pregnant, you have three options to think about — abortion, adoption, and parenting.

If you choose abortion, you can have it done in the clinic, in a hospital or by another doctor or nurse, now or later in your pregnancy. But, there are more risks the longer you wait to have an abortion.

We can talk about any of these options with you, and help you with whatever you decide to do.

What are the risks of the abortion pill?
Using the abortion pill is very safe. But, there are risks with any medical procedure. Your risk may be higher if you are not healthy.

Risks linked with the abortion pill are

- **The pregnancy doesn't end** — Sometimes the medicines do not end the pregnancy. Since they may cause serious birth defects, you will need to take additional medicines or have an abortion in a clinic or a hospital if the pregnancy continues.
- **Incomplete abortion** — This means some of the pregnancy tissue may be left inside the uterus (womb). This may lead to heavy bleeding, infection, or both. If this happens, you may need an abortion in a clinic or a hospital. Other tests or treatments may be needed.
- **Blood clots in the uterus** — Clots may cause cramping and belly pain. You may need a procedure if that happens.
- **Bleeding too much or too long** — This may require treatment with medicine, a suction procedure, or a blood transfusion.
- **Infection of the uterus** — Most infections can be found and treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have surgery to treat the infection.
- **Allergic reaction** — Some women are allergic to the medicines that are used.
- **Death** — Death from medication abortion is very rare. The risk of death from a full-term pregnancy and childbirth is much greater.

What are the warning signs of a problem?
Call us right away if you have

- **Belly pain** — This includes feeling sick, being weak, having nausea or diarrhea, or throwing up. It should not last longer than 24 hours after you take the second medicine. Call us right away if they do. Any one of them may be a sign of a serious infection. Or it could be another problem, like ectopic pregnancy. (That is a pregnancy that grows outside the womb.)
- **Heavy Bleeding** — Call us right away if you soak through two thick, full-size sanitary pads every hour for two hours in a row. Or call us if you think your bleeding is too heavy. One out of every 100 women will bleed so much that that they need a surgical procedure to stop it.
- **Fever** — Call us right away if you have a fever of 100.4°F or more if it lasts for 4 hours and it happens during the few days after you take the second pills. Fever that high can be a sign of serious infection. Or it could be another problem, like ectopic pregnancy.

What else do I need to know?
We will give you instructions on how to take care of yourself during the abortion. We will give you a time to return to Planned Parenthood for a follow-up visit.

No promise can be made about the outcome of your abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns please call us at the health center. We are happy to help you.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

Signature of any other person consenting _____ Date _____ Relationship to client _____

I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

Witness signature _____ Date _____

Physician signature _____ Date _____

Health Center Contact Info		
ASHEVILLE 828-252-7928	**BLACKSBURG** 540-951-7009	**CHAPEL HILL** 866-942-7762
CHARLESTON 843-628-4380	**CHARLOTTE** 704-536-7233	**CHARLOTTESVILLE** 434-296-1000
COLUMBIA 803-256-4908	**DURHAM** 866-942-7762	**FAYETTEVILLE** 866-942-7762
GREENSBORO 336-373-0678	**RALEIGH** 919-833-7534	**ROANOKE** 540-562-3457
VIENNA 304-295-3331	**WILMINGTON** 910-762-5566	**WINSTON-SALEM** 336-768-2980

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

04/16/2014

Dr. James Ray Dingfelder, CEO
Eastowne Ob-Gyn And Infertility
180 Providence Rd #3
Chapel Hill, NC 27514

RE: Recertification

Dear Dr. James Ray Dingfelder:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the survey conducted April 15, 2014. The purpose of conducting the survey was to evaluate the facility's compliance with the North Carolina Rules Governing the Certification of Clinics for Abortions. As discussed during the exit, there were no deficiencies found.

Should you have questions concerning the investigation, please do not hesitate to call me at (919) 855-4620.

Sincerely,

Regina Rashed, RN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Enclosed: State form Statement of Deficiencies

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0024	A. BUILDING: _____ B. WING _____	04/15/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EASTOWNE OB-GYN AND INFERTILIT	180 PROVIDENCE RD #3 CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS An onsite recertification survey was conducted 04/15/2014 and no deficiencies were found.	E 000		

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0024	A. BUILDING: _____ B. WING _____	07/23/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EASTOWNE OB-GYN AND INFERTILIT	180 PROVIDENCE RD #3 CHAPEL HILL, NC 27514

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS An unannounced, onsite relicensure survey was conducted on July 23, 2015. No deficiencies were cited.	E 000		

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 31, 2015

Dr. James Dingfelder
Eastowne Ob-Gyn And Infertility
180 Providence Rd #3
Chapel Hill, NC 27514

RE: State Licensure Survey

Dear Dr. Dingfelder:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the State Licensure Survey conducted July 23, 2015. The purpose of conducting the survey was to evaluate the facility's compliance with the North Carolina Rules for Licensing Abortion Clinics.

As discussed in the exit conference, there were no deficiencies cited as a result of the survey.

Should you have questions concerning the investigation, please do not hesitate to call me at (919) 218-9458.

Sincerely,

Lynn Ethridge

Lynn Ethridge, RN, BSN
Nurse Consultant
Acute and Home Care Licensure and Certification Section